UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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In re Biogen Idec, Inc. Securities Litigation	:	**Civil Action No. 05-cv-10400 (RCL)**
	:	
	:	**CLASS ACTION**
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	:	
	:	**JURY TRIAL DEMANDED**
	X	

CONSOLIDATED CLASS ACTION COMPLAINT
FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

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1. Lead Plaintiffs, by their undersigned attorneys, for their Consolidated Class Action Complaint (the "Complaint"), make the following allegations against Defendants based upon an investigation conducted by and under the supervision of Lead Counsel for Lead Plaintiffs, which has included, among other things: (i) interviews of former employees of Biogen Idec, Inc. ("Biogen" or the "Company") and Elan Corporation PLC ("Elan"); and (ii) review and analyses of: Defendants' public filings, including filings with the Securities and Exchange Commission ("SEC"); press releases issued by Defendants; news articles and analysts' reports concerning Defendants; transcripts from conference calls Defendants held with analysts; official records of regulatory actions taken by government agencies with respect to Biogen; official records in other relevant actions; scientific publications; and studies and information received from Freedom of Information Act ("FOIA") requests to the Food and Drug Administration ("FDA").[1]

2. Except as alleged herein, the underlying information relating to Defendants' misconduct and the particulars thereof is not available to Lead Plaintiffs or the public, but lies within the possession and control of Defendants and other Biogen insiders, thus preventing Lead Plaintiffs from further detailing Defendants' misconduct at this time. Lead Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

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[1] The FDA is an agency within the U.S. Department of Health and Human Services. Its mission is "to promote and protect the public health by helping safe and effective products reach the market in a timely way," "to monitor products for continued safety after they are in use," and "to help the public get the accurate, science-based information needed to improve health." *See* http://www.fda.gov/oc/opacom/fda101/sld001.html.

I. NATURE OF THE ACTION

3. Lead Plaintiffs bring this action, pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of themselves and all similarly situated persons or entities (collectively, the "Class") who purchased Biogen common stock between February 18, 2004 and February 28, 2005, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

4. This securities class action is predicated upon serious misstatements and omissions of material fact by the Defendants herein concerning the purported safety and projected market share of one of Biogen's leading drugs, Tysabri®, which Defendants falsely marketed during the Class Period as a "blockbuster" drug. Defendants developed Tysabri to treat multiple sclerosis ("MS"), a neurological disease that attacks the central nervous system, as well as Crohn's Disease and Rheumatoid Arthritis ("RA"), and as the drug progressed through expedited FDA approval, aggressively represented to investors that it was an innovative therapy with virtually no serious side effects, while at the same time Company insiders sold ***2,289,749 shares*** of Biogen stock for proceeds of approximately ***$137,233,850***.

5. As the Company would later admit, Defendants were aware that numerous undisclosed severe opportunistic[2] infections indicative of severe immunosuppression had occurred during the Tysabri clinical trials, prior to Defendants' application to the FDA, and prior to the drug's approval by the FDA. By failing to disclose these infections to the FDA, the

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[2] Opportunistic infections occur when ordinarily benign organisms infect individuals with severely impaired immune systems. These benign organisms may be viruses, bacteria, fungi or parasites that very rarely infect healthy humans with intact immune systems. Opportunistic organisms are different than more aggressive and readily transmissible infectious agents that routinely produce illness in healthy humans, such as influenza virus, pneumococcal pneumonia, cold viruses, etc. Examples of opportunistic infections are discussed further below.

Defendants were able to obtain "fast-track" approval of Tysabri, allowing them to accelerate the introduction of the drug to the market.

6. Indeed, documents submitted to the FDA confirm that Defendants concealed numerous known opportunistic infections from the FDA, prior to applying for, and receiving, fast-track approval of Tysabri. Specifically, according to a November 23, 2004 memorandum to Karen Weiss, M.D., Director at the FDA, from David Ross, M.D., Ph.D., Deputy Director on the FDA committee that approved Tysabri, the data that the Company submitted to the FDA did not include any evidence of opportunistic infections resulting from the drug. In this regard, Dr. Ross stated that: "[t]he events reported ***do not appear to represent infections due to opportunistic pathogens***." Moreover, the FDA documents that outline the scope of Tysabri approval, made no mention of any opportunistic infections, or any associated risks. These documents clearly demonstrate that the FDA was not fully informed with respect to the opportunistic infections that occurred in the Tysabri clinical trials. Based upon the limited information presented to the FDA, the drug was approved for the broadest possible market.

7. Defendants were ultimately forced to withdraw Tysabri from the market on February 28, 2005, only three months after FDA approval on November 23, 2004, because at least one patient on Tysabri, participating in the MS clinical trials, had contracted Progressive Multifocal Leukoencephalopathy ("PML") and another patient in that trial died from PML.[3] On March 1, 2005, Defendants further revealed that a third patient in the Tysabri Crohn's Disease clinical trials, misdiagnosed with a type of brain cancer in 2003, had actually died from PML.

[3] PML is an ***invariably always fatal disease*** of the central nervous system specifically associated with severe immunosuppression typically contracted by persons with Acquired Immune Deficiency Syndrome ("AIDS"). Indeed, investors would ultimately be told after the Class Period that Tysabri reduced the immune system of patients on the drug to the level of an AIDS patient.

Dr. Lawrence Steinman, a physician and the co-inventor of Tysabri, who had previously criticized Tysabri as being too dangerous, and communicated his views on the drug to the Defendants prior to the Class Period, declared in a March 1, 2005 *New York Times* article that, with respect to the three cases of PML, ***"I knew it was going to happen sooner or later***."

8. At the FDA Advisory Committee Hearing on March 7-8, 2006 (the "March 2006 FDA Hearing"), which was conducted to determine whether Tysabri should be returned to the market, Defendants revealed that the two patients who contracted PML in the MS trials, had actually began exhibiting signs of PML as early as November 2004. However, Defendants did not disclose these facts to the public or withdraw the drug until February 28, 2005, nearly three months later and after one patient had already died. Moreover, at the March 2006 FDA Hearing, the Defendants finally admitted that numerous other patients had developed serious opportunistic infections from the drug, which were previously not disclosed to the investment community or the FDA.

9. By concealing the truth concerning Tysabri's risks, Defendants were able to personally profit from substantial and unlawful insider selling. In particular, Defendant Thomas Bucknum, Executive Vice President and General Counsel of Biogen, ***was able to sell 89,700 shares of Biogen stock, reaping approximately $1.9 million*** in proceeds from such sale on February 18, 2005. Defendant Bucknum executed this sale after learning at approximately 12:00 p.m. that day at a meeting with other Biogen senior officers that a patient participating in the Tysabri clinical trials had been diagnosed with PML.

10. As a result of Defendant Bucknum's insider selling, the SEC filed a settlement enforcement action complaint (the "SEC Complaint") against him based upon his violations of the Securities Act of 1933 and the Exchange Act, as well as his breach of fiduciary duty to the

Company and its investors. Accordingly, the SEC announced that it had ***entered into a settlement agreement with Bucknum to pay $3 million in disgorgement, interest and penalties and prohibiting Bucknum from serving as an officer or director of a public company for five years***. On March 9, 2005, Biogen announced that Defendant Bucknum had "resigned from the company" as a result of insider trading allegations.

11. In addition to Defendant Bucknum, the Individual Defendants, themselves, sold approximately ***1,393,515 shares*** of Biogen stock during the Class Period for proceeds of approximately ***$84,212,688***.

12. Moreover, on February 17, 2005, only eleven days before Defendants withdrew Tysabri from the market, the Board of Directors of Biogen approved the payment of substantial bonuses to Defendants, which were based largely upon the Company's financial performance and product development. Indeed, each of the Individual Defendants herein received bonuses of as much as 140% of their annual compensation.

13. Despite their knowledge of the significant risks associated with Tysabri, throughout the Class Period, Defendants made materially false and misleading statements and omissions concerning the Company's current business and performance and prospects, as well as the market for and safety profile of Tysabri.

14. Specifically, Defendants made the following materially false and misleading statements:

- March 2, 2004 conference call - Defendant Mullen stated that "[w]e do believe that this innovative therapy will offer hope to a large number of patients and ***the market will grow significantly*** in the U.S. and Europe." [Emphasis added].

- April 30, 2004 earnings release - Defendant Mullen stated "[T]he Company is ***well-positioned to fulfill ANTEGREN's blockbuster potential."*** [Emphasis added].

- July 28, 2004 press release - Defendant Rohn stated: "We are convinced of Antegren's blockbuster potential. . . and ***believe Antegren will not only expand the market but also capture a lion's share of the market***." [Emphasis added].

- October 27, 2004 conference call - Defendant Adelman stated: "ANTEGREN should expand the market and ***become the number 1 therapy for MS***." [Emphasis added].

- November 23, 2004 press release - Defendant Mullen stated: "We believe Tysabri will ***revolutionize the treatment of MS and become the leading choice for patients and physicians***. [Emphasis added].

- November 24, 2004 press release - Defendant Mullen stated: "We certainly believe that ***Tysabri will move quickly in the first line therapy and become the number one MS product worldwide***." [Emphasis added].

- November 24, 2004 Joint Conference Call - "TYSABRI appears to be safe and well tolerated and have reassuring safety profile."

- February 7, 2005 Conference Call - "TYSABRI meets the needs with a new way to fight MS . . . with a good tolerability and safety profile."

15. For the reasons set forth herein, the foregoing statements were each materially false and misleading because, among other reasons: (i) Tysabri had serious, undisclosed side effects that occurred as a result of the drug's suppression of the immune system, leaving patients vulnerable to life-threatening infections, including PML; and (ii) due to its substantial risks to patients, Tysabri would be limited to patients in the most advanced stages of MS and, thus, the potential market for Tysabri was only a fraction of the purported $4 billion market that Defendants represented.

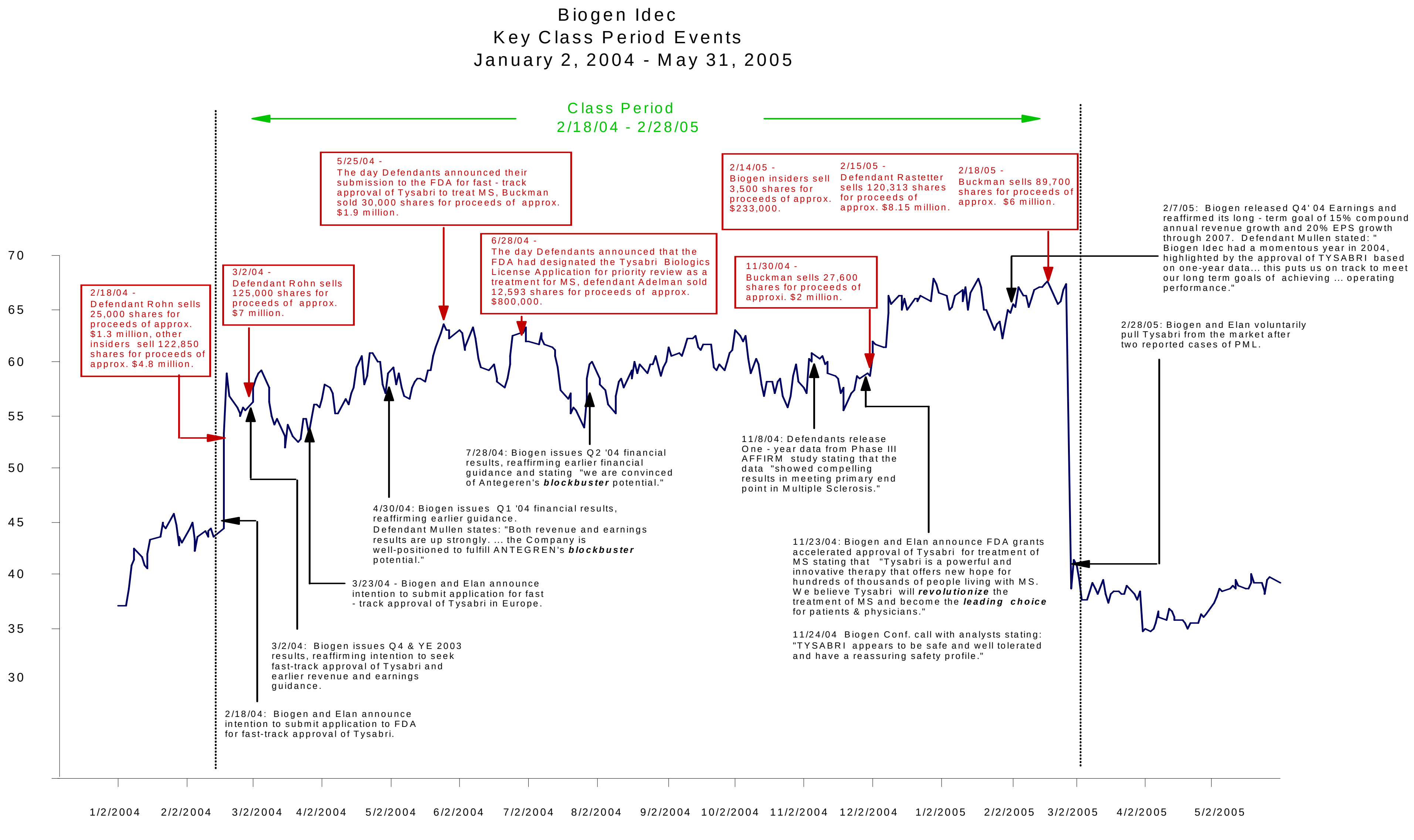
16. In reaction to the February 28, 2005 withdrawal of Tysabri, the stock market reaction was swift and severe, erasing approximately $9.6 billion dollars in shareholder value in one day, leaving Biogen with market capitalization of only $13 billion. Specifically, on February 28, 2005, Biogen shares plunged 42.5 %, falling $28.63 to close at $38.65 on trading volume of 118 million shares, more than thirty times the average daily trading volume during the

Class Period. Notably, this volume was nearly four times the highest trading volume in Biogen's history. Comparatively, on that same day, the S&P 500 Index decreased only 2.6% and the S&P Biotechnology Index increased 1.7 %.

17. On June 5, 2006, the FDA announced that it had approved the return of Tysabri to the market for treating MS, but recommended that Tysabri ***only*** be used as a last resort therapy for MS patients in which no other therapy was tolerable or effective. Not surprisingly, however, the FDA imposed landmark protocols which now serve to severely limit and restrict usage of the drug, including significant restrictions on the label and monitoring of patients taking Tysabri. Specifically, the FDA required Defendants to include a "***black-box***" warning, its strictest warning, on the Tysabri label and required Defendants to implement a stringent risk management plan, as detailed herein. This requirement extinguished any possibility of the widespread market distribution of Tysabri that Defendants had promised throughout the Class Period.

18. In reaction to the significant restrictions imposed on Tysabri, analysts sharply cut their rating of Biogen common stock and substantially lowered the future estimates of sales from Tysabri. Moreover, according to one analyst, "it appears that, despite [Tysabri's] efficacy, the ***safety concerns shrouding Tysabri are likely to have bulldozed its potential indefinitely***." Moreover, another analyst for Piper Jaffray, who slashed her estimate for worldwide Tysabri sales to just $21 million for 2006, down from $123 million, or 83%, noted that physicians she had spoken with confirmed that they were adopting Tysabri at a much slower rate than expected, because of safety concerns and patient-monitoring requirements.

19. The following chart indicates particularly significant events that took place during the Class Period, including Defendants' false and misleading statements, compared to a graph of Biogen's stock price movement and Defendants insider selling, during that period:



Biogen Idec
Key Class Period Events
January 2, 2004 - May 31, 2005
Class Period
2/18/04 - 2/28/05
5/25/04 - The day Defendants announced their submission to the FDA for fast - track approval of Tysabri to treat MS, Buckman sold 30,000 shares for proceeds of approx. $1.9 million.
2/14/05 - Biogen insiders sell 3,500 shares for proceeds of approx. $233,000.
2/15/05 - Defendant Rastetter sells 120,313 shares for proceeds of approx. $8.15 million.
2/18/05 - Buckman sells 89,700 shares for proceeds of approx. $6 million.
2/7/05: Biogen released Q4' 04 Earnings and reaffirmed its long - term goal of 15% compound annual revenue growth and 20% EPS growth through 2007. Defendant Mullen stated: " Biogen Idec had a momentous year in 2004, highlighted by the approval of TYSABRI based on one-year data... this puts us on track to meet our long term goals of achieving ... operating performance."
6/28/04 - The day Defendants announced that the FDA had designated the Tysabri Biologics License Application for priority review as a treatment for MS, defendant Adelman sold 12,593 shares for proceeds of approx. $800,000.
11/30/04 - Buckman sells 27,600 shares for proceeds of approxi. $2 million.
3/2/04 - Defendant Rohn sells 125,000 shares for proceeds of approx. $7 million.
2/18/04 - Defendant Rohn sells 25,000 shares for proceeds of approx. $1.3 million, other insiders sell 122,850 shares for proceeds of approx. $4.8 million.
2/28/05: Biogen and Elan voluntarily pull Tysabri from the market after two reported cases of PML.
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7/28/04: Biogen issues Q2 '04 financial results, reaffirming earlier financial guidance and stating "we are convinced of Antegeren's ***blockbuster*** potential."
11/8/04: Defendants release One - year data from Phase III AFFIRM study stating that the data "showed compelling results in meeting primary end point in Multiple Sclerosis."
4/30/04: Biogen issues Q1 '04 financial results, reaffirming earlier guidance.
Defendant Mullen states: "Both revenue and earnings results are up strongly. ... the Company is well-positioned to fulfill ANTEGREN's ***blockbuster*** potential."
11/23/04: Biogen and Elan announce FDA grants accelerated approval of Tysabri for treatment of MS stating that "Tysabri is a powerful and innovative therapy that offers new hope for hundreds of thousands of people living with MS. We believe Tysabri will ***revolutionize*** the treatment of MS and become the ***leading choice*** for patients & physicians."
3/23/04 - Biogen and Elan announce intention to submit application for fast - track approval of Tysabri in Europe.
11/24/04 Biogen Conf. call with analysts stating: "TYSABRI appears to be safe and well tolerated and have a reassuring safety profile."
3/2/04: Biogen issues Q4 & YE 2003 results, reaffirming intention to seek fast-track approval of Tysabri and earlier revenue and earnings guidance.
2/18/04: Biogen and Elan announce intention to submit application to FDA for fast-track approval of Tysabri.
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II. JURISDICTION AND VENUE

20. This action arises under Sections 10(b), 20(a), and 20A of the Exchange Act, as amended, 15 U.S.C. §§ 78j(b), 78(n) and 78t(a), 78(t)-1(a), and SEC Rule l0b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder.

21. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78a.

22. Venue is proper in this district pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). Many of the acts alleged herein, including the dissemination of materially false and misleading information in connection with the sale of a security, occurred in this district.

23. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the United States mails, interstate telephone communications, internet communications, and the facilities of the National Association of Securities Dealers Automated Quotations ("Nasdaq") market.[4]

III. PARTIES

A. Lead Plaintiffs

24. Lead Plaintiff New Jersey Carpenters Pension & Annuity Funds ("New Jersey Pension") was established by the Trustees of the Pension Fund, composed of Employer Trustees

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[4] The Nasdaq is an American electronic stock exchange, founded in 1971 by the National Association of Securities Dealers ("NASD"), who divested it in a series of sales in 2000 and 2001. It is owned and operated by The Nasdaq Stock Market, Inc. (NASDAQ: NDAQ) which was listed on its own stock exchange in 2002, under NDAQ. Nasdaq is the largest electronic screen-based equity securities market in the United States. With approximately 3,300 companies, it lists more companies and, on average, trades more shares per day than any other U.S. market.

representing employers in the industry and Employee Trustees representing various Carpenters and Millwright Local Unions and District Councils in the State of New Jersey. The Annuity Plan, a defined contribution plan, was established on May 1, 1982. During the Class Period, New Jersey Pension purchased Biogen common stock at artificially inflated prices and has been damaged by Defendants' wrongdoing. New Jersey Pension previously filed a certification in this Court in connection with the Motion of the Biogen Institutional Investor Group for Consolidation, Appointment as Lead Plaintiff, and Approval of Lead Plaintiffs' Selection of Co-Lead Counsel and Liaison Counsel ("Lead Plaintiff Motion") reflecting its transactions in Biogen common stock during the Class Period, which is incorporated by reference herein.

25. Lead Plaintiff Folksam Asset Management ("Folksam") is one of Sweden's largest asset managers and invests in assets on the equity, bond and money markets. During the Class Period, Folksam purchased Biogen common stock at artificially inflated prices and has been damaged by Defendants' wrongdoing. Folksam previously filed a certification in this Court in connection with the Lead Plaintiff Motion reflecting its transactions in Biogen common stock during the Class Period, which is incorporated by reference herein.

26. Lead Plaintiff Third Millennium Trading, LLP ("Third Millennium") is a limited liability partnership, with offices located in Chicago, Illinois and New York City, and specializes in proprietary equity trading. In this regard, the firm employs sophisticated proprietary traders who exclusively use the firm's own capital to trade securities. Third Millennium is also a fully reporting member of the NASD, is registered with the SEC, and is a member of the Chicago Board Options Exchange ("CBOE"), the American Stock Exchange and the Chicago Mercantile Exchange. Third Millennium purchased Biogen common stock at artificially inflated prices during the Class Period and has been damaged by Defendants' wrongdoing. Third Millennium

previously filed a certification in this Court in connection with the Lead Plaintiff Motion reflecting its transactions in Biogen common stock during the Class Period, which is incorporated by reference herein.

27. Lead Plaintiff Deerfield Beach Non-Uniformed Municipal Employees Retirement Plan ("Deerfield") administers funds for employees of the city of Deerfield Beach, Florida. Deerfield purchased Biogen common stock at artificially inflated prices during the Class Period and has been damaged by Defendants' wrongdoing. Deerfield previously filed a certification in this Court in connection with the Lead Plaintiff Motion reflecting its transactions in Biogen common stock during the Class Period, which is incorporated by reference herein.

28. Lead Plaintiff Plumbers and Pipefitters Local No. 520 Pension Fund ("Local No. 520") purchased Biogen common stock at artificially inflated prices during the Class Period and has been damaged by Defendants' wrongdoing. Local No. 520 previously filed a certification in this Court in connection with the Lead Plaintiff Motion reflecting its transactions in Biogen common stock during the Class Period, which is incorporated by reference herein.

29. Lead Plaintiff Horatio Capital LLC ("Horatio") is a limited liability company, headquartered in Chicago, Illinois and a proprietary firm specializing in the trading of securities products. Horatio is also a member of the NYSE Arca. Horatio purchased Biogen common stock at artificially inflated prices during the Class Period and has been damaged by Defendants' wrongdoing. Horatio previously filed a certification in this Court in connection with the Lead Plaintiff Motion reflecting its transactions in Biogen common stock during the Class Period, which is incorporated by reference herein.

30. By Order dated September 13, 2006, the Court affirmed the Honorable Magistrate Judge Marianne B. Bowler's recommendation to appoint New Jersey Pension, Folksam, Third Millennium, Deerfield, Local No. 520 and Horatio as the "Lead Plaintiffs" in this case.

B. Defendants

31. Defendant Biogen is a public company incorporated under the laws of Delaware, maintaining its principal executive offices at 14 Cambridge Center, Cambridge, MA 02142. Biogen common stock is actively traded on the Nasdaq National Market under the symbol BIIB. The Company describes itself "[a]s a global leader in the development, manufacturing, and commercialization of novel therapies" that "transforms scientific discoveries into advances in human healthcare." Biogen IDEC was formed in November 2003, when Biogen, Inc. and IDEC Pharmaceuticals Corporation merged under the name Biogen IDEC, Inc.

32. During the Class Period, Biogen had four commercial products: Avonex® (Interferon beta-1a) for the treatment of relapsing MS, RITUXAN® (rituximab) and ZEVALIN® (ibritumomab tiuxetan), both of which treat certain B-cell non-Hodgkin's lymphomas, also referred to as B-cell NHLs (a type of cancer), and AMEVIVE® (alefacept) for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. In addition to Tysabri, Biogen markets and sells two other monoclonal antibodies, Rituxan® and Zevalin®. Like Tysabri, Rituxan® and Zevalin® are monoclonal antibodies. Accordingly, Defendants herein had substantial experience with immunosuppressive drugs of this type and, thus knew or recklessly disregarded the serious risks associated with Tysabri. Biogen's revenue and earnings are highly dependent upon only two products, Avonex® and Rituxan®, which comprise the majority of its revenue. Together, these two products constituted 84% and 83% of the Company's total revenue in 2004 and 2005,

respectively. During the Class Period, the only major product in Biogen's drug development pipeline was Tysabri.

33. Defendant William H. Rastetter, PhD was, at all relevant times, the Company's Executive Chairman and a Biogen Director. Defendant Rastetter also made materially false and misleading public statements during the Class Period in Company press releases, conference calls with analysts and in Biogen public filings with the SEC. During the Class Period, Defendant Rastetter unloaded approximately 582,045 shares of Biogen common stock for proceeds of approximately $35,346,019, while privy to material, non-public information, which had not been disclosed to the investing public, including Plaintiffs and Class members who purchased Biogen common stock contemporaneously with the sales by Defendant Rastetter. Defendant Rastetter has significant experience and is highly educated in the biotechnology industry and, accordingly, would have understood the serious risks of Tysabri. For example, from 1982 to 1984, Defendant Rastetter served in a scientific capacity at Genentech, directing the Biocatalysts and Chemical Sciences groups. From 1975 to 1982, he held various faculty positions at the Massachusetts Institute of Technology. Moreover, Defendant Rastetter also currently serves as a Director on the board of Illumina, Inc., a company that develops parallel, miniaturized and flexible biosensors and on the California Healthcare Institute. Defendant Rastetter received his PhD in Chemistry from Harvard University in 1975.

34. Defendant James C. Mullen was, at all relevant times, the Company's Chief Executive Officer and President. Defendant Mullen also made materially false and misleading public statements during the Class Period in the Company's press releases, public filings with the SEC, quarterly conference calls with analysts and at periodic healthcare conferences with analysts. During the Class Period, Defendant Mullen dumped approximately 192,000 shares of

Biogen common stock for proceeds of approximately $11,727,370, while privy to material, non-public information, which had not been disclosed to the investing public, including Plaintiffs and Class members who purchased Biogen common stock contemporaneously with the sales by Defendant Mullen. Defendant Mullen, like Defendant Rastetter, has significant experience and education in the biotechnology industry. Specifically, from 1984 to 1988, Defendant Mullen held various positions at SmithKline Beckman Corporation (now GlaxoSmithKline plc), and currently holds a B.S. in Chemical Engineering from Rensselaer Polytechnic Institute and a M.B.A. from Villanova University. Defendant Mullen also serves on the Board of Trustees of Rensselaer Polytechnic Institute and on the Board of Directors of the Biotechnology Industry Organization.

35. Defendant Peter N. Kellogg was, at all relevant times, the Company's Executive Vice President, Finance and Chief Financial Officer. Defendant Kellogg also made materially false and misleading public statements during the Class Period in the Company's press releases, public filings with the SEC and quarterly conference calls with analysts.

36. Defendant William Rohn was, at all relevant times, the Company's Chief Operating Officer. Defendant Rohn also made materially false and misleading public statements during the Class Period in the Company's public filings with the SEC and quarterly conference calls with analysts. During the Class Period, Defendant Rohn sold approximately 350,000 shares of Biogen common stock for proceeds of approximately $20,182,209, while privy to material, non-public information, which had not been disclosed to the investing public, including Plaintiffs and Class members who purchased Biogen common stock contemporaneously with the sales by Defendant Rohn. Defendant Rohn, like Defendants Mullen and Rastetter, has significant experience and education in the biotechnology industry and has been employed by several

biotechnology companies, including Adria Laboratories, Abbott Laboratories, Warren-Teed Pharmaceuticals, Miles Laboratories and Mead Johnson Laboratories. Defendant Rohn has also served on the Board of Directors of several biotechnology companies, including Pharmacyclics, a pharmaceutical company and Cerus Corporation, a company that develops medical systems and therapeutics.

37. Defendant Burt A. Adelman, M.D. was, at all relevant times, the Company's Executive Vice President of Development. Defendant Adelman also made public statements during the Class Period in the Company's press releases, public filings with the SEC, quarterly conference calls with analysts and at periodic healthcare conferences with analysts. During the Class Period, Defendant Adelman unloaded approximately 80,870 shares of Biogen common stock for proceeds of approximately $5,009,008, while privy to material, non-public information, which had not been disclosed to the investing public, including Plaintiffs and Class members who purchased Biogen common stock contemporaneously with the sales by Defendant Adelman. Similarly, Defendant Adelman is well-educated and experienced in the biotechnology industry. Since 1992, Defendant Adelman has served as a lecturer at Harvard Medical School and is currently a member of the Board of Directors for the New England Healthcare Institute.

38. Defendant Thomas Bucknum was the Company's Executive Vice President and General Counsel from November 2003 until March 9, 2005, when Biogen announced that Defendant Bucknum had "resigned from the company," as a result of his improper insider trading. Plaintiffs bring a claim against Defendant Bucknum solely pursuant to Section 20A of the Exchange Act. As alleged herein, Defendant Bucknum unloaded approximately 188,600 shares of Biogen common stock for proceeds of approximately $11,948,082, while privy to material, non-public information, which had not been disclosed to the investing public, including

Plaintiffs and Class members who purchased Biogen common stock contemporaneously with the sales by Defendant Bucknum.

39. Defendants Rastetter, Mullen, Kellogg, Rohn and Adelman are referred to collectively herein as the "Individual Defendants."

40. Defendants Rastetter, Mullen, Kellogg, Rohn, Adelman and Bucknum are referred to collectively herein as the "Section 20A Defendants."

C. Control Person Liability

41. During the Class Period, the Individual Defendants, as senior executive officers and directors of Biogen, were privy to confidential and proprietary information concerning Biogen and its business, operations, performance, and prospects, including its compliance with applicable federal, state and local laws and regulations. Because of their high-level positions with Biogen, the Individual Defendants had regular access to non-public information about its regulatory compliance, business, operations, performance, and prospects through access to internal corporate documents and information, conversations and connections with other corporate officers and employees, attendance at management meetings and the Company's Board of Directors, and committees thereof, and reports and other information provided to them in connection therewith.

42. Because of their possession of the information described above, the Individual Defendants knew, or recklessly disregarded the significant risks associated with Tysabri's severe immunosuppressive effect and consequently, the liability the Company faced as a result of serious opportunistic infections that were guaranteed to occur. Defendants knew or recklessly disregarded that these risks had not been disclosed to, and were being concealed from the investing public, and that, as a result of the risks posed by Tysabri, the potential market for Tysabri was only a fraction of what Defendants represented. Accordingly, Defendants knew, or

recklessly disregarded that the statements complained of herein were materially false and misleading when made.

43. Each of the Defendants is liable as a direct participant and primary violator with respect to the wrongdoing complained of herein. In addition, the Individual Defendants, by reason of their status as senior executive officers and directors, were "controlling persons" within the meaning of § 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to, and did, directly and indirectly, control the conduct of Biogen's business.

44. The Individual Defendants, because of their positions with the Company, controlled and/or possessed the authority to control the content of the various SEC filings, press releases, and other public statements made by the Company during the Class Period. By reason of their respective high-level management and Board positions, the Individual Defendants had the ability and opportunity to review copies of Biogen's SEC filings, reports and press releases alleged herein to be materially misleading, prior to, or shortly after their issuance, and to prevent their issuance or cause them to be corrected.

D. Group Pleading

45. The Individual Defendants are liable for the materially false and misleading statements pleaded herein that were issued by or in the name of the Company, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants, each of whom was intimately involved in the day-to-day operations of Biogen. It is appropriate to treat the Individual Defendants as a group and to presume that the public filings, press releases, and other public statements complained of herein, are the product of the collective actions of the narrowly defined group of Individual Defendants. The Individual

Defendants, by virtue of their high-level positions within Biogen, directly and actively participated in the management and day-to-day operations of the Company, and were privy to confidential non-public information concerning the business and operations of Biogen. In addition, the Individual Defendants were involved in drafting, reviewing, and/or disseminating the materially false and misleading statements issued by Biogen and approved or ratified those statements, and, therefore, adopted them as their own.

E. Duties Of The Individual Defendants

46. Each of the Individual Defendants had the duty to make full, candid and timely disclosures of all material facts relating to the business, operations, performance, and prospects of Biogen. Among other things, Defendants were required to:

- conduct and supervise the business of Biogen in accordance with all applicable laws and regulations;
- supervise the preparation of the Company's SEC filings and approve any reports concerning the financial reporting and results of Biogen;
- ensure that Biogen established and followed adequate internal controls; and
- refrain from obtaining personal benefit, at the expense of the public purchasers of Biogen common stock, by misusing proprietary non-public information.

47. As senior officers and controlling persons of a publicly-held Company whose common stock was, during the relevant time, registered with the SEC pursuant to the Exchange Act, traded on the Nasdaq, and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's performance, operations, business, and prospects, and to correct any previously issued statements that were or had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based upon truthful and accurate information.

48. As a result of Defendants' failure to fulfill the foregoing obligations, Biogen's common stock was artificially inflated during the Class Period. As the truth emerged, Lead Plaintiffs and other members of the Class (defined below) were damaged. In response to the emergence of the truth, Biogen's common stock fell precipitously. As a direct and proximate result of Defendants' wrongdoing, Lead Plaintiffs and other Class members were damaged.

IV. CLASS ACTION ALLEGATIONS

49. Lead Plaintiffs bring this class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of a class of persons who purchased Biogen common stock during the Class Period (or their successors in interest). Excluded from the Class are the Defendants named herein, members of the immediate families of the Defendants, any firm, trust, partnership, corporation, officer, director or other individual or entity in which a Defendant has a controlling interest or which is related to or affiliated with any of the Defendants, and the legal representatives, heirs, successors in interest or assigns of any such excluded person.

50. Also excluded from the Class are all Defendants named in the action captioned, *In re Elan Corp. Securities Litigation*, No. 05-CV-2860 (RJH), currently pending in the Southern District of New York (the "Elan Individual Defendants") and members of the immediate families of the Elan Individual Defendants, any firm, trust, partnership, corporation, officer, director or other individual or entity in which the Elan Individual Defendants has a controlling interest or which is related to or affiliated with any of the Elan Individual Defendants, and the legal representatives, heirs, successors in interest or assigns of any such excluded person.

51. The Class is so numerous that joinder of all members is impracticable. During the Class Period, there were more than 344,027,240 shares of Biogen common stock issued and outstanding. Biogen shares were actively traded on the NASDAQ exchange. During the Class Period, the average daily volume of Biogen common stock that trades on the NASDAQ was

approximately 3,898,146 shares. While the exact number of Class members is unknown to Lead Plaintiffs at this time and can only be ascertained through appropriate discovery, Lead Plaintiffs believe that there are thousands of geographically dispersed Class members. Record owners and Class members can be identified from records maintained by Biogen or its transfer agent and can be notified of the pendency of this action by mail and publication, using forms of notice similar to those customarily used in securities class actions.

52. Lead Plaintiffs' claims are typical of the members of the Class, because Lead Plaintiffs and all of the Class members sustained damages arising from the same wrongful conduct complained of herein.

53. Lead Plaintiffs will fairly and adequately protect the interests of the members of the Class, and Lead Plaintiffs have no interests which are contrary to, or in conflict with, the interests of the Class members that they seek to represent. Lead Plaintiffs have retained competent counsel experienced in class action litigation under the federal securities laws to ensure such protection, and intend to prosecute this action vigorously.

54. Questions of law and fact common to the members of the Class predominate over any questions that may affect only individual members, in that, Defendants have acted on grounds generally applicable to the entire Class. The questions of law and fact common to the Class include:

- whether Defendants' acts violated the federal securities laws as alleged herein;
- whether Defendants' publicly disseminated press releases and statements during the Class Period omitted and/or misrepresented material facts and whether Defendants breached any duty to convey material facts or to correct material facts previously disseminated;
- whether Defendants participated in and pursued the common course of conduct complained of herein;

- whether Defendants acted with scienter in omitting and/or misrepresenting material facts;
- whether the price of Biogen common stock was artificially inflated during the Class Period as a result of the material misrepresentations and omissions complained of herein;
- whether Defendants Rastetter, Mullen, Kellogg, Rohn and Adelman were controlling persons as alleged herein; and
- whether members of the Class have sustained damages and, if so, the proper measure of such damages.

55. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation make it impossible for the members of the Class to individually seek redress for the wrongs done to them. There will be no difficulty in the management of this action as a class action.

V. BACKGROUND AND FACTS UNDERMINING THE VERACITY OF DEFENDANTS' CLASS PERIOD REPRESENTATIONS

A. Multiple Sclerosis Is A Severe Autoimmune Disease

56. MS is a severe autoimmune disease[5] that affects the central nervous system ("CNS"), which consists of the brain, spinal cord and optic nerves. Surrounding and protecting the nerve fibers of the CNS is a fatty tissue called myelin, which helps nerve fibers conduct electrical impulses.

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[5] Autoimmune diseases cause the immune system to adversely target the cells, tissues, and organs of one's own body.

57. In patients with MS, immune cells migrate into the CNS causing inflammation. Such inflammation destroys the myelin, or nerve fiber itself, in multiple areas, leaving scar tissue called sclerosis. These damaged areas are known as plaques or lesions.

58. Myelin not only protects nerve fibers, but is essential to their function. Thus, when the myelin or nerve fiber is destroyed or damaged, the ability of the nerves to conduct electrical impulses to and from the brain is disrupted, and this disruption produces the various symptoms of MS, including progressive physical disability and eventually cognitive impairment. Individuals affected by MS typically have problems with coordination and balance, damaged vision and abnormal sensation.

59. The natural progression of MS varies among patients. Some patients are minimally affected by the disease for many years, while others patients experience rapidly progressive disease leading to total disability or even death, within a few years. MS is classified into the following categories, according to the stage and type of the disease:

> **Relapsing-remitting MS** – This category of MS is characterized by acute exacerbations followed by periods of complete or incomplete recovery. In the initial stages of MS, approximately 80-90% of individuals have relapsing-remitting MS.
>
> **Secondary progressive MS** – This category of the disease involves gradual neurological deterioration with or without superimposed relapses. Approximately 50% of those with relapsing-remitting MS will enter the secondary progressive phase of the disease within ten to fifteen years of disease onset.
>
> **Primary progressive MS** – This form of MS is characterized by a steady progression of disability with few or no exacerbations. Approximately 10% of individuals with MS exhibit this form of the disease.
>
> **Progressive relapsing MS** – This category of the disease is characterized by progressive MS from the onset with infrequent superimposed relapses. This form is relatively uncommon and occurs in less than 5% of patients.

60. There is no cure for MS and existing treatments provide only modest benefits to patients. MS has conventionally been treated through the use of different types of drugs, such as

beta-interferons, glatiramer acetate, steroids and other immunosuppressive drugs. Proprietary drugs currently available in the United States to treat MS patients include: (i) Avonex® (a beta-interferon marketed by Biogen); (ii) Betaseron® (a beta-interferon marketed by Schering AG); (iii) Rebif® (a beta-interferon marketed by Serono Pharma); (iv) Copaxone® (a glatiramer acetate marketed by Teva Neuroscience); and (v) Novantrone® (an antineoplastic marketed by Serono Pharma). All of these therapies, however, have proven to be marginally effective in most MS patients and often carry intolerable side effects such that some patients choose to forego any treatment.

B. Progressive Multifocal Leukoencephalopathy

61. PML is an almost always fatal disease of the nervous system caused by a polyomavirus (the "JC Virus") that typically strikes people with severely impaired immune systems, such as persons with AIDS. PML presents symptoms such as impaired cognition, cortical blindness and weakness on one side of the body. PML usually results in death within one to four months of the onset of the disease.

62. The JC virus, which causes PML, is latent in the kidneys of almost all adults following infection in childhood adolescence and only invades the brain when the immune system is severely impaired, which allows the virus to replicate uncontrollably.

C. Tysabri

63. Tysabri is scientifically referred to as a "humanized monoclonal antibody" and the "first alpha-4 integrin antagonist in the new selective adhesion molecule ('SAM') inhibitor class."[6] Tysabri works by binding to a specific receptor on white blood cells, called

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[6] Tysabri is a trademarked name. Tysabri was formerly known as Antegren until the FDA caused Biogen and Elan to change the name to avoid confusion with other drugs with similar names. The terms Tysabri, Antegren and natalizumab all refer to the same drug, which is now

lymphocytes, thereby preventing such white blood cells' normal migration in the body and thereby suppressing both inflammation and normal immune responses in the body. Thus, Tysabri, by its very nature, is a highly immunosuppressive drug.

64. Tysabri was developed in the early 1990's by Dr. Lawrence Steinman, Professor of Neurology and Immunology at Stanford University and Dr. Ted Yednock of Athena Neurosciences (acquired by Elan in 1996), among others, as part of a collaborative academic experiment. Drs. Steinman and Yednock studied the effects of Tysabri in mice with experimental autoimmune encephalomyelitis ("EAE"), a condition pathologically similar to MS, and concluded that Tysabri successfully prevented migration of lymphocytes and monocytes (another type of white blood cell) to the brain, thus preventing inflammation in the brains of mice with EAE. These results indicated that Tysabri might be effective in treating MS. Drs. Steinman and Yednock also concluded, however, that Tysabri ***prevented migration of lymphocytes and monocytes to other organs as well.*** Thus, by preventing migration of these white blood cells (lymphocytes) – the body's primary defense mechanism for fighting infections – to the bodily organs other than the brain, patients that developed infections in other organs were defenseless to fight the infection.

65. For this reason, the widespread application of the drug posed serious concerns. Dr. Steinman's most significant concern was that since Tysabri prevented white blood cells from migrating to ***all*** organs in the body, its effects could not be localized to only the CNS. As a result, patients taking Tysabri would be vulnerable to serious, potentially life-threatening opportunistic infections because white blood cells could not reach the infected area to fight the

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commonly known as Tysabri. These terms are used interchangeably throughout this Consolidated Class Action Complaint.

infection. According to Dr. Steinman, people with MS are not unusually susceptible to infectious diseases, but generally handle infections quite well. However, when MS patients began taking Tysabri, Dr. Steinman concluded that such patients become much more susceptible to opportunistic infections.

66. The results and conclusions of Dr. Steinman's study were published in a March 5, 1992 article entitled, "Prevention of Experimental Autoimmune Encephalomyelitis By Antibodies Against α4β1 Integrin," in the journal, *Nature*, (356:63-6, 1992), well before the Class Period.

67. Tysabri is an extremely dangerous drug that virtually "turns off" the immune system. This result can lead to the onslaught of PML by allowing the JC virus (discussed above) to replicate in the CNS of patients taking Tysabri. As indicated above, Defendants were forced to withdraw Tysabri from the market on February 28, 2005 because, among other reasons, two patients in the MS Tysabri clincial trials were diagnosed with PML.

D. Biogen Collaborated With Elan On The Marketing, Development And Commercialization Of Tysabri

68. On August 17, 2000, Biogen and Elan announced, in a joint press release, that they had entered into an Antegren Development and Marketing Collaboration Agreement (the "Collaboration Agreement" or "Agreement"), for the "exclusive" and mutual benefit of both, to work collaboratively to expedite the development, regulatory approval and commercialization of Tysabri, under which the parties would share equally, revenue and costs (the "August 17, 2000 Press Release"). In the August 17, 2000 Press Release, Defendant Mullen described Tysabri as a drug with "blockbuster potential."

69. At the time of the Collaboration Agreement, Elan and Biogen contemplated use of Tysabri for treating MS, Crohn's Disease and RA. The Collaboration Agreement required that

Biogen and Elan "work exclusively with each other to research, Develop, manufacture and Commercialize Licensed Products in the Field . . . ." According to a former Director of Drug Metabolism and Pharmacokinetics for Elan Pharmaceutical from June 2003 to April 2004 ("CS 1"), Biogen joined forces with Elan to capitalize on the development of Tysabri that Elan had already completed.

70. The Collaboration Agreement established a Joint Steering Committee (the "JSC") to "oversee and manage the Development and Commercialization activities contemplated by this Agreement." As discussed below, the Collaboration Agreement required two teams that reported to the JSC, the Joint Project Team ("JPT") and the Joint Commercialization Team ("JCT") to implement the development and marketing of Tysabri. Thus, information and results learned by either Biogen or Elan concerning positive or negative results of the drug was shared with the other company pursuant to the Agreement.

71. The JSC was comprised of six members, three representatives from Biogen and three from Elan. At least two representatives from each party were required to be senior members of management, either a "vice-president or more senior officer." The third representative was required to be someone of a "suitable authority and seniority who has significant experience or expertise in biopharmaceutical drug research, development commercialization or marketing." CS 1 confirmed that pursuant to the Collaboration Agreement, Biogen and Elan created a committee comprised primarily of senior management from both companies to monitor the progress of Tysabri.

72. In addition to its general responsibilities to oversee and coordinate the development of Tysabri according to the Development Plan, pursuant to the Collaboration Agreement, the JSC was charged with the responsibility to: (i) direct "the overall strategy,

timing, goals and direction of Development activities . . . and provide direction to the Joint Project Team;" (ii) "review and approve global regulatory and clinical strategies;" (iii) "approve the Development Plan and each Annual Workplan/Budget;" (iv) "review and approve the determinations of the Joint Project Team with respect to the calculations of the presence or absence of a Commercially Significant Indication;" and (v) "perform such other functions as are allocated to it. . . ."

73. Before each meeting, JSC members received written copies of materials used at JSC meeting presentations. The JSC could also request, at any time, "information related to Development or Commercialization activities or that a written report be prepared in advance of any meeting summarizing certain material data . . . ."

74. As stated above, the Collaboration Agreement also called for a Joint Project Team (JPT), consisting of representatives from Biogen and Elan with technical scientific expertise, who were responsible for, among other things, preparing and executing Development activities, preparing the Development Plan and Annual Work Plan/Budget, as outlined in the Collaboration Agreement, and selecting the criteria for developing Tysabri, including decisions on design and implementation of research programs and clinical trials. The JPT was also required to submit various written reports to the JSC concerning its duties.

75. The Joint Commercialization Team (JCT) was comprised of three to five members from each party – Biogen and Elan – with experience in the commercialization and marketing of pharmaceutical products. The JCT was responsible for preparing the Commercialization Plan and each Annual Commercialization Budget, as outlined in the Collaboration Agreement, overseeing and implementing commercialization activities, and

"coordinating with the [JPT] in developing and implementing standard operating procedures for adverse event reporting and compliance with regulatory requirements. . . ."

76. Under Article 3.5 of the Collaboration Agreement - Meetings of Chief Executive Officers – Defendant Mullen, Biogen's CEO and Kelly Martin, Elan's CEO – were required to "meet two (2) times per year during the term of [the] Agreement" to review the progress of the collaboration and any important issues that arise. As Defendant Mullen admitted during conference calls for the second and third quarters of 2004, discussed further below, "[Biogen] and [its] partner, Elan, have been meeting regularly to formulate these launch plans [of Tysabri]. Kelly Martin and [Defendant Mullen] are in frequent communications. ***We believe these investments will provide healthy returns to the business, given ANTEGREN's blockbuster potential***." [Emphasis added]

77. The Collaboration Agreement - Article 4.3 - Clinical Trials, requires that "all clinical data and reports related to the clinical trials . . . shall be jointly owned by the Parties [Biogen and Elan], and each Party shall have full use. . . ."

78. Article 13 governs adverse event reporting and requires, in relevant part:

> 13.1 INFORMATION. Biogen and Elan will disclose and make available to each other in a timely manner all preclinical, clinical, regulatory, commercial and other information concerning Licensed Products and constituting Know-how . . .
>
> * * *
>
> 13.3 ADVERSE EVENTS. Each Party will be responsible for the safety surveillance and pharmacovigilance regulatory obligations with respect to the Licensed Product in those territories where it is the sponsor of non-clinical or clinical development . . . or where it is the license holder of the Licensed Product's Regulatory Approval. Each party shall provide to the responsible Party under this Section with data on all adverse drug experience reports related to the Licensed Product in each case in accordance with procedures established by the [JPT] or the [JCT] or pursuant to an adverse event reporting agreement entered into by the Parties.

> Elan and Biogen agree to fulfill all their safety surveillance and pharmacovigilance regulatory obligations with respect to the Licensed Product.

79. Thus, under the Collaboration Agreement, senior executives at Biogen and Elan, including Defendant Mullen and Elan's CEO, Kelly Martin, were charged with approving and closely monitoring the progress of the development and marketing of Tysabri, including the manner in which clinical trials were designed and conducted, the tracking of adverse events, the resolution of issues as they arose and communication of findings to one another.

E. <u>The Tysabri Clinical Trials</u>

1. FDA Requirements Regarding Clinical Trial Testing

80. Before a drug may be marketed and sold commercially in the United States, FDA regulations require that it first be tested for safety and efficacy in animals to determine its potential toxicity. Drugs that demonstrate acceptable safety profiles and benefits may be approved by the FDA for testing in clinical trials using human volunteers. According to the FDA, "[i]t's important . . . that people make their decision to participate in a clinical trial only after they have a full understanding of the entire process and the risks that may be involved."

81. Clinical trials using human volunteers are conducted in various phases. The FDA requires a company to conduct three phases before a drug can be marketed and sold to the general population. The first phase ("Phase I") is conducted using a small number of healthy people for the purpose of determining the proper dosage of a drug, documenting how it is metabolized and excreted and identifying acute side effects. The second phase ("Phase II") includes participants who have the condition the product may potentially treat and seeks to gather further safety data and preliminary evidence of the drug's efficacy. If Phase II indicates that the drug may be effective in treating a disease, and the risks are acceptable given the observed efficacy and the severity of the disease, the drug moves on to the third phase ("Phase

III"), which tests the product's effectiveness and monitors side effects in a larger population of patients and control subjects.

82. Biogen and Elan conducted clinical trials purportedly to test the safety and efficacy of Tysabri as a treatment for MS, Crohn's Disease and RA. Although under the Collaboration Agreement, Biogen and Elan were both responsible for the trials and required to communicate all details associated with the clinical trials to one another, Biogen was primarily responsible for running the MS trials and Elan was primarily responsible for running the Crohn's and RA trials.

2. FDA Requirements For "Fast-Track" Approval, Priority Review And Accelerated Approval Of New Drug Applications

83. The term "fast-track" approval refers to an expedited process for interacting with FDA during drug development. The FDA permits a company to apply for "fast track" approval if the drug "addresses an unmet medical need." *See* http://www.accessdata.fda.gov/scripts/cder/onctools/Accel.cfm#FastTrack. The benefits of fast-track approval include scheduled meetings to seek FDA input into development plans, the option of submitting a New Drug Application in sections rather than all components simultaneously, and the option of requesting evaluation of studies using surrogate endpoints. *Id.*

84. "Priority Review," relates to the time frame the FDA targets for reviewing a completed application and is a designation for an application after it has been submitted to the FDA for review and approval of a marketing claim. *See* http://www.accessdata.fda.gov/scripts/cder/onctools/Accel.cfm#Priority. Under the Food and Drug Administration Modernization Act (FDAMA), reviews for "new drug applications" are designated as either standard or priority. A standard designation sets the target date for completing all aspects of a review and the FDA taking action on the application (approve or not

approve) at 10 months after the date it was filed. A priority designation sets the target date for the FDA action at 6 months. The FDA grants priority review status to products that are considered to be potentially significant therapeutic advancements over existing therapies that address an unmet medical need.

85. "Accelerated Approval" is a program that is intended to make promising products for life threatening diseases available on the market on the basis of preliminary evidence prior to formal demonstration of patient benefit. *See* http://www.accessdata.fda.gov/scripts/cder/onctools/Accel.cfm#SubpartH. If accelerated approval is granted, the approval that is granted may be considered a provisional approval with a written commitment to complete clinical studies that formally demonstrate patient benefit.

86. On May 25, 2004, Defendants announced that they had submitted a Biologics License Application to the FDA for fast-track approval of Tysabri for treating patients with MS, based upon only one year's worth of data from the Phase III of the Tysabri MS clinical trials. On June 28, 2004, Defendants announced that the FDA had designated Tysabri for "priority" review and "accelerated approval" for the treatment of MS, which still required Defendants to complete Phase III testing of Tysabri. On November 23, 2004, Defendants announced that the FDA granted accelerated approval of Tysabri based on one-year data from two Phase III studies, the AFFIRM monotherapy trial and the SENTINEL add-on trial with Avonex®.

3. The MS Clinical Trials Of Tysabri

87. Pre-clinical animal studies to evaluate Tysabri as a treatment for autoimmune diseases, like MS and Crohn's Disease, were conducted beginning in the early 1990s. Phase I of the Tysabri MS clinical trials was completed by Athena Neurosciences in December 1995.

88. In September 2001, Biogen and Elan presented promising data from Phase II of the Tysabri MS trials at the annual meeting of the European Congress on Treatment and

Research in Multiple Sclerosis. The Phase II trials were purportedly double-blinded,[7] placebo-controlled studies that evaluated Tysabri's effect on inflammatory lesions in the brain of patients with MS and assessed the tolerability and clinical benefit of Tysabri. According to Biogen and Elan, the primary analysis was based on magnetic resonance imaging ("MRI") scans and purportedly demonstrated that MS patients treated with Tysabri for six months had fewer lesions known as "gadolinium-enhancing lesions" (characteristic of MS) than patients treated with a placebo. The data also purportedly demonstrated that the number of MS relapses over the treatment period, one of the pre-specified clinical endpoints in the trial, was also reduced. Specifically, in the placebo group, there were thirty-four relapses as compared to the Tysabri 3 mg/kg group and Tysabri 6 mg/kg group, which had nineteen and fourteen reported relapses, respectively.

89. Phase III of the Tysabri MS testing began in December 2001 and consisted of two trials: (1) the AFFIRM trial; and (2) the SENTINEL trial. The AFFIRM trial was purportedly a two-year, randomized, multi-center, placebo-controlled, double-blinded study of approximately 900 patients, designed to determine whether Tysabri effectively slowed the rate of disability in MS patients and reduced the rate of clinical relapses. The SENTINEL trial purportedly evaluated the safety and efficacy of Tysabri used in combination with Biogen's other MS drug, Avonex® (Interferon beta-1a), in patients with relapsing-remitting MS. The SENTINEL trial was also a two-year, randomized, multi-center, placebo-controlled, double-blinded study of approximately 1,200 patients, designed to determine whether, in combination with Avonex®,

[7] A double-blinded study is "a study in which at least two separate groups receive the experimental medication or procedure at different times, with neither group being made aware of when the experimental treatment or procedure has been given." *See* http://www.medterms.com/script/main/art.asp?articlekey=11177.

Tysabri was more effective than Avonex® alone in slowing the rate of disability in MS and in reducing the rate of clinical relapses.

90. On February 18, 2004, Defendants announced their intention to apply for fast-track approval for treatment of Tysabri in MS patients after only one year of data in the Phase III clinical trials, which was disclosed to investors on November 8, 2004.

4. The Crohn's Disease Trials Of Tysabri

91. On May 23, 2001, Biogen and Elan issued a joint press release announcing that Phase II of the Tysabri Crohn's Disease trial was complete and indicated "promising results on multiple endpoints." Phase III of the Crohn's trials, which began in December 2001, consisted of two trials: (1) ENACT-1 (to evaluate clinical responses to Tysabri and its ability to induce remission of disease); and (2) ENACT-2 (to evaluate the duration and effects of Tysabri). The ENACT-2 study only enrolled patients who participated in the ENACT-1 study. On July 24, 2003, Defendants announced that ENACT-1 did not meet the primary endpoint of "response." According to Defendants:

> This result appears to be due to a larger than expected placebo response rate. However, data from the study indicate that the biological activity of natalizumab was similar to that seen in the Phase II study published in the New England Journal of Medicine earlier this year. Additionally, there were no notable differences in the overall rates of side effects between natalizumab and placebo treatment groups through week 12.

92. On January 29, 2004, Defendants issued a press release announcing that the ENACT-2 trial had "met its primary endpoint." At the same time, Defendants began an additional Phase III induction trial, the ENCORE trial, because the original Phase III induction trial (ENACT-1) did not meet its primary endpoint. The ENCORE trial was designed to be a double-blinded, placebo-controlled study of 510 patients at 114 sites to evaluate the safety and efficacy of intravenous Tysabri in patients with moderately to severely active Crohn's Disease.

5. The Rheumatoid Arthritis Trials Of Tysabri

93. During mid-2004, Defendants began the Phase II RA trials. This RA trial was a multi-center, double-blinded, placebo-controlled study measuring the efficacy, safety and tolerability of intravenous Tysabri in patients with moderate to severe RA receiving concomitant treatment with methotrexate, an antimetabolite drug, which blocks the metabolism of cells and thus has been found useful in treating certain cancers, among other diseases.

6. The Suspension Of All Clinical Trials Of Tysabri Upon Defendants' Withdrawal Of The Drug From The Market

94. On February 28, 2005, Defendants suspended all of its Tysabri clinical trials and withdrew Tysabri from the market, pending an investigation into two patients enrolled in the MS trials that were diagnosed with PML. At the time of the February 28, 2005 announcement, the status of the clinical trials was as follows:

- <u>MS Clinical Trials</u> - Phase III of the AFFIRM study was competed and Phase III of the SENTINEL study was substantially completed.
- <u>Crohn's Disease Clinical Trials</u> - Two Phase III studies were completed and one Phase III Induction trial was in progress.
- <u>RA Clinical Trials</u> - Phase II had been underway for approximately eight months.

95. As each of the phases in these clinical trials were completed and thus, the results unblinded, Biogen and Elan, as a matter of course, would have exhaustively studied and analyzed the data. Thus, by at least February 2004, when Biogen and Elan announced their intention to apply to the FDA for fast-track approval of Tysabri for treatment of MS, Defendants would have completed a thorough analysis of the completed phases of the clinical trials, including Phase II of the MS trials and all phases of the Crohn's Disease trials. Moreover, before Defendants received FDA approval in November 2004, they would have also fully analyzed the one-year data from the Phase III MS trials.

F. Defendants Knew Or Recklessly Disregarded Numerous Warnings Of Tysabri's Severe Immunosuppressive Effects

96. As discussed above, Biogen is the third largest American biotechnology company. Moreover, the Individual Defendants are highly experienced and educated in the biotechnology industry. Accordingly, Defendants had the ability to, and did, keep themselves highly apprised of all facts and information concerning the drugs that they were developing in order to market and sell them commercially. Defendants were particularly focused on Tysabri, which they claimed would be the next "***blockbuster***" drug that would "***revolutionize***" the treatment of MS. In fact, Tysabri's success as a blockbuster drug was critical to Biogen's ability to grow its business, given that Biogen was dependant upon two other drugs in their mature stages, for more than eighty percent of its revenue. A drug in its mature stage has reached its maximum revenue and earnings potential. Thus, a company cannot further grow its business without tapping into a new market.

97. Prior to filing an application with the FDA for fast-track approval of Tysabri, Defendants knew or recklessly disregarded the following red flags, confirming that the market for Tysabri would be only a fraction of that disclosed by Defendants because of the significant risks associated with Tysabri that were to result in opportunistic infections: (i) Tysabri, by its very nature because of the way it worked, was an immunosuppressive drug that left patients vulnerable to serious opportunistic infections; (ii) animal studies indicated that Tysabri worked to turn off the immune system; (iii) similar warnings were made in publications in scientific and medical journals regarding the severe immunosuppressive effects of Tysabri; (iv) scientific meetings were held where top scientists discussed the serious and inherent risks of Tysabri; and (v) numerous serious opportunistic infections that had already occurred in patients participating in Tysabri clinical trials, confirmed prior data indicating how dangerous Tysabri actually is.

Moreover, several confidential sources have corroborated that Defendants knew of the severe immunosuppressive effects of Tysabri, and of the resulting adverse events that occurred during the Tysabri clinical trials, before the Class Period, which Defendants never publicly disclosed.

1. Tysabri Is A Highly Dangerous Immunosuppressive Drug Making It A Certainty That Severe Opportunistic Infections Would Occur In Patients On Tysabri

98. Unbeknownst to Class members during the Class Period, Tysabri, is a highly dangerous immunosuppressive drug that prevents white blood cells from migrating to an infected area of the body. Accordingly, taking Tysabri leaves the patient vulnerable to developing serious opportunistic infections.

99. According to an Administrative Director in the Department of Neurology for Caritas St. Elizabeth's Medical Center in Boston, MA from 2004 through May 2006 who established a Multiple Sclerosis Clinic where this witness worked with Tysabri ("CS 2"), Tysabri raised a red flag when it comes to the issue of vulnerability to infection.

100. Thus, Defendants knew or recklessly disregarded that Tysabri, given its very nature, carried the substantial risk that patients taking the drug would develop serious, frequently life-threatening opportunistic infections. As a result, Defendants knew or recklessly disregarded that the market for Tysabri would, at best, only be a fraction of the purported market represented to investors, and would be limited to only those in the most advanced stages of MS for which no other MS therapy worked.

2. Animal Studies Warned Defendants That Tysabri Was A Highly Immunosuppressive Drug That Could Cause Potentially Life-Threatening Opportunistic Infections

101. Animal studies beginning in the early 1990's conducted by Defendants, themselves, as well as renowned scientists, revealed that Tysabri posed a significant risk that

life-threatening opportunistic infections would occur in patients taking the drug because it prevented immune cells from migrating to ***any*** organs in the body to fight infection.

102. However, Defendants, knew, or recklessly disregarded the results of these animal studies because Defendants knew that if they disclosed the truth about the severe risks inherent in Tysabri, the market for Tysabri would be only a fraction of the $4 billion market that Defendants had promised investors and, thus, they would lose hundreds of millions of dollars already invested in developing Tysabri.

103. Defendants, along with Elan, conducted several animal studies demonstrating that Tysabri was highly immunosuppressive. As discussed below, these animal studies resulted in numerous, unexplained deaths in animals injected with as little as one dose of Tysabri. These animal studies, the results of which were made available to senior executives at both Biogen and Elan, include the following:

- **Athena NeuroSciences Study #AL077** (8/10/95) – Two unexplained deaths in Tysabri-treated guinea pigs.
- **Athena NeuroSciences Study #961011** (1/8/97) – One Tysabri-treated cynomolgus monkey died of undetermined causes. Pathology reported hepatorenal failure possibly due to fatal fatty liver-kidney syndrome, although the monkey did not fit such a diagnosis.
- **Biogen Study # 309-010-01** (9/24/01) – Unexplained deaths among Tysabri-treated guinea pigs attributed to hypersensitivity reactions. Masses were noted under the skin of these animals, but no pathological examination was performed to check for malignancies that might be due to severe immunosuppression.
- **Elan Study #309-008-01** (11/21/01) – Unexplained deaths of pregnant female guinea pigs after taking Tysabri, attributed to the process of giving birth, although there were no such deaths among control guinea pigs.
- **Elan Study #309-007-01** (1/22/02) – Unexplained deaths of a number of male guinea pigs after an initial dose of Tysabri, attributed to anaphylaxis (a sudden, severe, potentially fatal, systemic allergic reaction). However, anaphylaxis was extremely unlikely because the guinea pigs had never been exposed to Tysabri.

- **Elan Study #309-028-02** (12/28/02) – Unexplained deaths of pregnant female guinea pigs treated with Tysabri. Technicians vaguely concluded that the deaths were "not related to test article."

104. In addition, as mentioned above, Dr. Lawrence Steinman concluded in an earlier animal study that Tysabri prevented migration of white blood cells to other organs in the body, leaving the body defenseless to fight serious and potentially life-threatening opportunistic infections.

105. Some examples of potential opportunistic infections that Dr. Steinman was concerned might occur, which he characterized as "horrendous infectious diseases," included atypical pneumonias, tuberculosis and brain abscesses. Accordingly, Dr. Steinman opined that, in light of the fact that Tysabri is not a cure for MS, and its severe immunosuppressive effects, Tysabri should not be used as a first-line therapy, but rather limited to only the most severe cases of MS.

106. Dr. Steinman reiterated his well-founded concerns about the serious risks that Tysabri posed to patients in another article published on July 9, 2004 in the journal, *Science*, (305:212-216, 2004), entitled "Immune Therapy for Autoimmune Diseases." In that article, Dr. Steinman stated: "[c]linical trials of drugs with unknown safety profiles should aim to exclude patients with normal or near-normal neurological examination and target those patients with relapsing-remitting multiple sclerosis at greater risk of disability . . . ." According to Dr. Steinman, Tysabri had:

> at least a theoretical concern that recipients of the therapy would become generally compromised in their ability to fight infection. This concern has been borne out in a phase 2 trial in MS, in which an increased rate of pharyngitis, a form of upper respiratory tract infection, was observed.

107. After this article was published, ***senior officials at Biogen, asked Dr. Steinman to "tone down" his criticism of Tysabri***. Indeed, Defendants did not want Dr. Steinman's

warnings to the medical and scientific communities to adversely affect the Company's targeted market for Tysabri.

108. A study ***funded by Elan*** and published in an August 11, 1999 article in the journal, *Neurology*, published by the *American Academy of Neurology*, (53:466-472, 1999), entitled "The Effect of Anti-[alpha]4 Integrin Antibody on Brain Lesion Activity in MS," (the "August 1999 Study") concluded that given the potential risks of Tysabri, "[f]urther studies will be required to determine the longer effect of this treatment . . . ." The article also questioned Tysabri's overall efficacy, as follows:

> [It] is important to note a significant increase in relapses in the treatment group compared to placebo during the second 12 weeks . . . our findings raise the possibility that ***there may be a rebound increase in the relapse rate after stopping treatment . . .*** The preliminary efficacy of Antegren (3mg/kg) in the treatment of MS has been shown in the study but the effect was modest and transient. [emphasis added]

109. In addition, Dr. Stephen D. Miller ***co-authored an article with Biogen scientist Carol L. Vanderlugt,*** which was ***contributed to by Dr. Cheryl Nickerson-Nutter, a Biogen researcher,*** among others, published in April 2001 in the *The Journal of Clinical Investigation*, entitled "Discordant Effects of Anti-VLA-4 Treatment Before And After Onset of Relapsing Experimental Autoimmune Encephalomyelitis," (107:995-1006, 2001) [hereinafter the "JCI Article"]. In that article, Dr. Miller concluded that, based upon the results of the effects of Tysabri in an animal study, "***these results suggest that treatment with anti-VLA-4 Ab has multiple effects on the immune system and may be problematic in treating established autoimmune diseases such as MS***." The study further indicated that Tysabri treatment either at the peak of the acute disease or during remission, actually "exacerbated relapses . . . ."

110. Moreover, according to the JCI Article:

> [O]ur results indicate that caution must be used when attempting to treat *established* Th1-mediated autoimmune diseases such as MS with intact mAb to VLA-4 [Antegren]. The exacerbation of R-EAE [the equivalent of MS in humans] in animals in which treatment [with Antegren] is initiated during the acute phase or during remission . . . . Caution regarding the potential use of intact anti-VLA-4 in human disease is also suggested by recent clinical trials on MS patients. Although designed specifically to only examine magnetic resonance imaging MRI lesions, relapse rates in patients treated with an anti-VLA-4 mAb were increased over controls, even though the therapy appeared to inhibit short-term development of new MRI lesions . . . ***Continued examination of the multiple effects of anti-VLA-4 and VLA-4 inhibitors have on the immune system will be required to resolve these important issues***. [Emphasis added].

111. Dr. Miller found the results of his research "alarming" and, thus, directly recommended to senior Biogen officials that they should conduct additional animal studies before Tysabri was tested in humans. Dr. Miller's recommendations included testing Tysabri in another animal model of MS that uses Theiler's virus (a central nervous system infection) to produce lesions in mice similar to those of MS patients. However, Defendants ignored Dr. Miller's warnings because of their dissatisfaction with the results of his studies, which called into question the safety and efficacy of Tysabri, and failed to conduct the additional recommended animal studies.

112. Moreover, the August 1999 Study and the JCI Article suggest that patients on Tysabri therapy who then discontinue the therapy, develop "rebound disease," where MS progresses at a more rapid pace than that prior to taking Tysabri. In other words, although Tysabri acts to slow-down the progression of MS, once the patient discontinues Tysabri therapy, MS progresses at a much faster pace, as if to catch up to the point where the disease would have progressed, if the patient had never been on Tysabri therapy.

3. Scientific And Medical Publications And Industry Conferences Indicated Tysabri's Severe Immunosuppressive Effects

113. In addition to the numerous animal studies described above, several scientific and medical publications, as well as physicians and other experts who spoke at industry conferences warned of the severe immunosuppressive effects of Tysabri. These publications and industry conferences were attended by a close knit group of physicians and other biotechnology experts, including Defendants herein.

114. Specifically, Dr. Elliott Obi-Tabot wrote a research paper for Serono Pharma International, a Swiss biotechnology company that competes with Biogen and Elan, where he was employed as a consultant, raising concerns about the potent immunosuppressive properties of Tysabri and concluded that serious opportunistic infections were a possible side effect of Tysabri.

115. In addition, a May 23, 2003 article, entitled "VLA-4 Antagonists: Potent Inhibitors of Lymphocyte Migration. Yang GX, Hagmann WK," Med. Res. Rev., at 369-92 (2003), warned that ***drugs like Tysabri block the function of the immune system and interfere with normal inflammatory responses to infection***.

116. A May 2006 article by Dr. Olaf Stuve, *et al*. in the journal, *Annals of Neurology*, (59:743-747, 2006), entitled "Immune Surveillance in Multiple Sclerosis Patients Treated with Natalizumab," [hereinafter, the "Olaf Study"] concluded that Tysabri therapy reduced a patient's immune system in the CNS to that of someone with AIDS. This study also found that, even if physicians could run tests to determine whether certain patients were at risk of subsequent opportunistic infections, "stopping [Tysabri] therapy at that time may not prevent the risk of a subsequent clinically evident infection" because Tysabri remains in the patient's system for a significant time period after therapy is discontinued.

117. In the Olaf Study, Dr. Stuve and his colleagues found that low lymphocyte counts persisted in the CNS ***six months*** after discontinuing Tysabri. A neurologist intimately involved with the MS Tysabri clinical trials ("CS 4") confirmed that, before Tysabri was approved by the FDA, senior management at Biogen and Elan were aware that Tysabri persisted in the body bound to lymphocytes for months after administration, leaving the patient vulnerable to opportunistic infections for a prolonged period, far longer than most immunosuppressive drugs.

118. Defendants frequently attended analyst conferences held within the scientific community where scientists and physicians discussed current events and key issues, including the risks of Tysabri. At one conference held in Venice, Italy in September 2004, Dr. Steinman warned about the risks of opportunistic infections from Tysabri. Similarly, Dr. Steinman made the same strong warnings about the risk of opportunistic infections caused by Tysabri in a formal scientific presentation at the Keystone Symposium, held in January 2005 in Montana, which Biogen co-sponsored, and which top Biogen scientists and physicians attended.

119. As discussed earlier, Dr. Steinman was in a unique position to offer such warnings given his expertise and status as a co-inventor of Tysabri. Moreover, opportunistic infections that occurred as a result of Tysabri therapy, validated Dr. Steinman's earlier warnings.

4. Defendants Were Aware Of Serious Adverse Events Occurring During Their Tysabri Clinical Trials, Confirming Prior Warnings Of Tysabri's Severe Immunosuppressive Effects And Failed To Disclose Those Events To The FDA

a. FDA Adverse Event Reporting Requirements

120. Defendants have now admitted, at a March 2006 FDA Hearing to determine whether to allow Tysabri to re-enter the market (discussed below), that serious opportunistic infections occurred in patients on Tysabri therapy during the Tysabri clinical trials, ***well before they applied for, and received fast-track approval from the FDA*** to market and sell Tysabri.

These opportunistic infections confirmed the prior warning discussed above, that Tysabri was a severely immunosuppressive drug that was certain to, and did, cause serious and sometimes life-threatening opportunistic infections. These opportunistic infections qualify as "serious adverse events" or "serious adverse drug events" according to FDA guidelines, and should have been disclosed to the public as well as the FDA when they occurred, prior to FDA approval.

121. The FDA defines an "adverse event" or an "adverse drug experience" as:

> Any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

21 C.F.R. § 314.80.[8]

122. A life-threatening adverse drug experiences is defined as:

> Any adverse drug experience that places the patient, in the view of the initial reporter, at ***immediate*** risk of death from the adverse drug experience as it occurred, i.e., it does not include an adverse drug experience that, had it occurred in a more severe form, might have caused death.

[8] The FDA's Adverse Event Reporting System ("AERS") "is a computerized information database designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. The ultimate goal of AERS is to improve the public health by providing the best available tools for storing and analyzing safety reports." *See* http://www.fda.gov/cder/aers/default.htm. "The FDA receives adverse drug reaction reports from manufacturers as required by regulation." *Id*. "Health care professionals and consumers also send reports voluntarily through the MedWatch program, which become part of a database." *Id.*

Id. (Emphasis added).

123. According to FDA regulations, Defendants were required to keep written documentation of all adverse events that occurred during the Tysabri clinical trials. 21 C.F.R. § 310.305(a) – "Records and Reports Concerning Adverse Drug Experiences on Marketed Prescriptions Drugs for Human Use Without Approved New Drug Applications" ("manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved new drug . . . application" must "establish and maintain records" of all adverse events); *see also* 21 C.F.R. § 312.32(b) (with respect to Investigational New Drug Applications, the sponsor "shall promptly review all information relevant to the safety of the drug obtained or otherwise received by the sponsor from any source . . . .").

124. Pursuant to FDA regulations, Defendants were also required to promptly report adverse events to the FDA. *See* 21 C.F.R. § 312.50 – "Responsibilities of Sponsors" ("Sponsors are responsible for . . . ***ensuring that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug"***) [Emphasis added]; 21 C.F.R. § 310.305(a) – "Records and Reports Concerning Adverse Drug Experiences on Marketed Prescriptions Drugs for Human Use Without Approved New Drug Applications" ("manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved new drug . . . application" must report to the FDA "all serious, unexpected adverse drug experiences associated with the use of their drug products."); 21 C.F.R. § 314.80 (same); 21 C.F.R. § 600.80 (same).

125. The sponsor of a drug is required to report such adverse events to the FDA associated with the drug "***that is both serious and unexpected . . . as soon as possible and in no event later than 15 calendar days after the sponsor's initial receipt of the information.***" *Id.*,

§ 312.32(c)(1)(i) [Emphasis added]. Moreover, the sponsor must notify the FDA of any "***unexpected fatal or life-threatening***" experience associated with the use of the drug as soon as possible but in no event later than 7 calendar days after the sponsor's initial receipt of the information." *Id.*, § 312.32(c)(2).

126. Despite Defendants' disclosure and reporting obligations under FDA regulations, as discussed below, Defendants failed to disclose any of the "opportunistic" infections that occurred during the Tysabri clinical trials to the FDA or to the public until after they received fast-track approval of Tysabri in November 2004. Defendants were motivated to conceal these serious opportunistic infections from the FDA in order to receive fast-track approval of Tysabri with the broadest label possible. Indeed, had the FDA had all of the facts concerning the serious adverse events that occurred in patients taking Tysabri, including the substantial number of serious opportunistic infections that occurred, the FDA may not have approved Tysabri at that time without additional extensive testing and would most certainly have required Defendants to include a prominent safety warning, as they have with other similar drugs, and have now required for Tysabri. Such additional testing however would have been very expensive and time consuming and would have resulted in delaying the introduction of Tysabri.

127. However, a prominent safety warning, such as a black-box warning, would have been devastating to Biogen because it would have limited the future market of Tysabri to only a fraction of that promised to investors and certainly would be much less than the "4+ billion dollars" in revenue that Defendants had promised throughout the Class Period.

128. Notably, other drugs like Tysabri, that are immunosuppressive monoclonal antibodies, typically have prominent black box warnings in their FDA approved labels cautioning about the severe immunosuppressive effects of those drugs and their potential serious

side effects. Indeed, Biogen is no stranger to these FDA regulations because Biogen, itself, markets two other monoclonal antibodies, Rituxan® and Zevalin®, which are used to treat certain types of cancers. Both of the labels for those drugs contain prominent warnings of the risk of immunosuppression and infections. In particular, the FDA approved label for Rituxan® warns of the risk of reactivation of Hepatitis B virus, severe liver injury and death. However, the markets for these drugs are limited given the risks associated with taking them.

b. Defendants Failed to Disclose Opportunistic Infections To The FDA, Prior To Receiving Fast-Track Approval Of Tysabri

129. As discussed below, Defendants knew of the serious opportunistic infections that occurred during the Tysabri clinical trials, but failed to disclose them to the FDA prior to receiving approval in November 2004. An exhaustive search of the FDA website revealed no evidence indicating that Defendants disclosed these serious opportunistic infections to the FDA until after fast-track approval. In fact, documents obtained from the FDA's website suggest the opposite – that Defendants specifically concealed "opportunistic" infections that occurred during the Tysabri clinical trials from the FDA.

130. For example, a November 23, 2004 Memorandum from David Ross, M.D., PhD Deputy Director on the FDA committee responsible for approving Tysabri, specifically stated: "[t]he events reported ***do not appear to represent infections due to opportunistic pathogens***." [Emphasis added]. Similarly, the FDA's Medical Review issued by the FDA's Center for Drug Evaluation and Research approving Tysabri for commercial use made no mention of the risks of Tysabri or any of the opportunistic infections that were likely to occur, and had occurred, in its safety discussion. Thus, as revealed by this sample of FDA documents, although the FDA apparently had some evidence suggesting adverse events occurred during the Tysabri clinical trials, Defendants clearly did not apprise the FDA of any "opportunistic" infections.

131. Defendants' knowledge of these serious opportunistic infections is evidenced by the following (discussed below): (i) Defendants' own admission at the March 2006 FDA Hearing; (ii) the Collaboration Agreement required Defendants to closely monitor and exhaustively review all aspects of all phases of the clinical trials; (iii) the Tysabri clinical trials for Crohn's Disease and MS were substantially completed by early 2004 and thus, Defendants had access to the data results; and (iv) confidential sources confirm Defendants knew of reported adverse events that were reported during clinical trials.

i. Facts Ultimately Admitted At The March 2006 FDA Hearing

132. During the March 2006 FDA Hearing to review Biogen and Elan's application for the return of Tysabri to the market, Defendants admitted that they were aware of numerous opportunistic infections that occurred during the Tysabri clinical trials, prior to FDA approval, which were not previously disclosed to the FDA.

133. Dr. Alice Hughes, an FDA participant, disclosed that the Tysabri clinical trial data showed ***seventeen deaths*** that had occurred in patients participating in the Tysabri clinical trials, ***thirteen of which were in patients taking Tysabri***. FDA Tr., 185. Among the causes of death were PML (two cases), malignant melanoma (one case), pulmonary aspergillosis (one case), and pnemocystis pneumonia (one case) - all but the melanoma being a serious opportunistic infection. FDA Tr. 185.

134. Dr. Michael Panzara, employed by Biogen, who presented safety data for Biogen and Elan, and Dr. Hughes, also explained that the Tysabri clinical trial data had revealed at least the following opportunistic infections that occurred during the Tysabri clinical trials: PML, herpes virus infections, cryptosporidial gastroenteritis, pneumocystis carinii pneumonia, pulmonary aspergillosis, CMV colitis, mycobacterium avium intracellular pneumonia, lower

respiratory tract infections, pulmonary tuberculosis, lung abscess and Burkholderia cepacia pneumonia. FDA Tr., 62-64, 180-81, 203-4. According to Dr. Hughes, these infections suggest "the possibility of a compromise in cell-mediated immunity." FDA Tr., 180.

135. During the March 2006 FDA Hearing, Dr. Panzara noted that herpes infections had occurred with greater frequency in Tysabri treated patients, particularly those using combination therapy and that this was true for both MS and Crohn's Disease patients. FDA Tr., 58-60, 66. Defendants directly attributed the increase in herpes infections to suppression of cell mediated immunity - the very risk that Defendants had been warned about for well over a decade. FDA Tr. 58.

136. According to Dr. Panzara, a herpes infection was the type of opportunistic infection that Elan and Biogen "chose to study to evaluate potential effects of natalizumab on cell-mediated immunity." FDA Tr., 54. Dr. Hughes echoed similar concerns related to the significant number of herpes-type infections, stating that the "types of infections that we observed suggest the possibility of a compromise in cell-mediated immunity." *Id.*, 180.

137. Dr. Panzara's concerns were correct. After Tysabri was approved in November 2004, two MS patients developed recrudescent herpes virus. One patient, who received a single dose of Tysabri in February 2005, developed herpes simplex type 2 encephalitis (a brain infection) and died as a result of the infection three months thereafter. FDA Tr., 57. The second herpes case involved a patient who contracted herpes simplex type 1 encephalitis after taking a single dose of Tysabri. *Id.* That patient fortunately is reported to have survived after appropriate treatment for the infection. *Id.*

138. During the March 2006 FDA Hearing, Dr. Hughes also expressed concerns that Tysabri "has the potential to increase the risk of cancer." FDA Tr., 175. Dr. Hughes was

particularly alarmed with the data in the Crohn's Disease clinical trials, which demonstrated that malignancies were more frequent in Tysabri treated patients as compared to placebo treated patients. *Id*. Dr. Hughes's concern arose from the common knowledge in the medical community that severely immunosuppressed individuals are at greater risk for developing certain malignancies.

139. Moreover, Dr. Panzara reported on a third case of PML that occurred in a patient in the Crohn's Disease trial, who was purportedly misdiagnosed in July 2003 with malignant astrocytoma (a type of brain cancer). FDA Tr., 61. After the two reported PML cases in the MS trials, Biogen and Elan re-reviewed this patient's medical records and determined that the patient died in December 2003 of PML, not malignant astrocytoma.

140. Dr. Panzara concluded that, based upon the data from pre and post clinical trials, "natalizumab" (Tysabri) treatment is associated with an increased risk of PML" and that "[t]here may also be an increased risk of other opportunistic infections." FDA Tr., 65.

ii. Biogen And Elan Admittedly Communicated Regularly Concerning Issues Related To Tysabri Pursuant To The Collaboration Agreement

141. According to the Collaboration Agreement, Defendants were charged with closely monitoring the Tysabri clinical trials and reporting any adverse events that occurred during the trials. Indeed, Defendant Mullen admitted in a July 28, 2004 earnings release (discussed further below) that "[w]e and our partner Elan have been meeting regularly to formulate the launch plan [of Tysabri]. Kelly Martin and I are in frequent communication on a variety of issues."

142. Accordingly, senior executives at Biogen, including the Individual Defendants, would have known about serious opportunistic infections that occurred in any of the Tysabri clinical trials by virtue of their duties under the Collaboration Agreement and their positions at Biogen.

iii. Confidential Sources Have Confirmed That Defendants Knew That Serious Opportunistic Infections Occurred During The Tysabri Clinical Trials

143. By January 2004, one month prior to announcing Biogen and Elan's intention to seek fast track approval of Tysabri, the Crohn's trials and Phase II of the MS trials were completed. By mid-year 2004, one-year data from Phase III of the MS trials was completed. Since the data from the completed trials would have been unblinded, Defendants would have had access to, and conducted as a matter of course, an exhaustive analysis of the data results in the trials. Accordingly, Defendants would have known about the opportunistic infections that occurred during the Tysabri clinical trials, discussed above.

144. Confidential sources confirm that Defendants knew of the serious opportunistic infections that occurred during the Tysabri clinical trials. For example, a neurologist formerly affiliated with the Yale University School of Medicine who was directly involved in the Tysabri clinical trials for MS ("CS 3") confirmed that several serious opportunistic infections occurred during the MS and Crohn's Disease trials. Among the opportunistic infections that CS 3 recalled, was a cryptosporidiosis infection (an opportunistic infection caused by a parasite) that occurred during the MS trials and pneumocystis carinii pneumonia and atypical mycobacterial infections that occurred during the Crohn's Disease trials. In CS 3's opinion, these earlier opportunistic infections constituted significant warnings to the Defendants about how immunosuppressive Tysabri actually is. None of these opportunistic infections, however, were disclosed to the FDA prior to Tysabri's approval in November 2004.

145. CS 3 also confirmed that Biogen had access to the data in the Crohn's trials that were run by Elan and that Biogen was fully aware of the opportunistic infections that had arisen during the Crohn's trials. CS 4 similarly confirmed that this witness was informed of serious opportunistic infections that occurred during the Tysabri Crohn's Disease clinical trials,

including pneumocystis carinii pneumonia and atypical mycobacterial infections. None of these opportunistic infections were disclosed to the FDA prior to Tysabri's approval in November 2004.

146. Moreover, in CS 3's opinion, many of the problems that occurred with Tysabri were the ***result of executives at Biogen being excessively aggressive in getting Tysabri to the market.*** According to CS 3***, Biogen executives pushed hard to get fast track designation and initial approval of Tysabri by the FDA with limited safety data***.

147. A neurologist involved in the SENTINEL Phase II trial in Glasgow ("CS 5") similarly noted that, during the clinical trials, ***it became obvious that continued use of Tysabri compromised the immune system.*** According to CS 5, the Crohn's Disease clinical trials revealed that Tysabri increased the risk of patients developing cancer. CS 5 recalled that five clinical trial participants contracted cancer as compared to one patient in the placebo group. CS 5 was particularly concerned with the types of cancer that patients had contracted. For example, CS 5 recalled one patient in the Crohn's Disease clinical trials taking Tysabri who developed malignant melanoma, a type of skin cancer, which was particularly unusual because MS patients do not typically get malignant melanoma. Moreover, according to CS 5, another patient taking Tysabri in the clinical trial developed cervical cancer, which is caused by human polyomavirus, a virus closely related to the JC virus that causes PML. CS 5 believed that if a disease such as MS was not curable, life-threatening treatments such as Tysabri were not appropriate. Again, none of the opportunistic infections were disclosed to the FDA prior to Tysabri's approval in November 2004.

148. Moreover, a former Data Entry Clerk for Randstad from May 2004 to December 2004 assigned to work with Biogen to track clinical trial results ("CS 6"), further confirmed that

a large volume of adverse events associated with Tysabri were being reported to Biogen - on average, between fifty and sixty adverse events were reported daily. CS 6 recalled that in June 2004 and just before Tysabri was approved in November 2004, the volume of adverse events was extremely high, particularly when compared to other clinical trials in which this witness was involved. CS 6 recalled that just before Tysabri was approved, there were approximately sixty to seventy adverse events reported daily.

149. CS 6 also recalled that many of the adverse events reported in 2004 were serious adverse events, including an increase in the size of tumors that resulted in patients being admitted to the hospital because of a loss in motor skills and complaints suggesting symptoms of PML. CS 6 recalled that approximately five to ten of every fifty adverse events were reported from a doctor's office via a physician's note or a call from the nurse. CS 6 was certain that ***Defendants were aware of any concerns relating to the Tysabri clinical trials***.

150. According to CS 2, there was a concern at Biogen that Tysabri might leave people unable to deal with other infections and that was something about which the scientific team was generally aware. Similarly, CS 6 recalled concerns within the Company about the fast-tracking of Tysabri.

151. Thus, by Defendants' own admission at the March 2006 FDA Hearing, they knew of serious opportunistic infections that occurred during the Tysabri clinical trials. However, Defendants never disclosed these severe infections to investors and instead, touted Tysabri as a "blockbuster" drug that would "revolutionize" the treatment of MS throughout the Class Period.

G. The FDA Adverse Event Report Contained Numerous Opportunistic Infections That Occurred In Patients On Tysabri Therapy, Confirming Prior Warnings That Such Infections Were Certain To Occur

152. A review of the Adverse Event Report data concerning Tysabri beginning with November 24, 2004, after Tysabri was approved, through March 2006, received from the FDA (the "Adverse Event Report") pursuant to Plaintiffs' FOIA request, confirms that patients on Tysabri therapy were vulnerable to developing serious and sometimes life-threatening opportunistic infections because Tysabri effectively turns off their immune systems leaving patients defenseless to fight such infections.

153. As summarized in the table below, a review of the Adverse Event Report concerning Tysabri, which contains adverse events reported after Tysabri was approved for public consumption, reveals that at least sixty opportunistic infections directly related to severe immunosuppression were reported in patients taking Tysabri as of the report date of March 2006.

Infection	**Number Reported**
Progressive Multifocal Leukoencephalopathy	3
Sepsis	11
Meningitis Herpes	11
Encephalitis Herpes	5
Pneumocystis Jiroveci Pneumonia	5
Gangrene	4
Pyelonephritis	3
Escherichia Sepsis	3
Septic Shock	2
Pneumocystis Jiroveci Infection	2
JC Virus Infection	2
Cryptogenic Organizing Pneumonia	2
Tuberculosis Gastrointestinal	1

Systemic Mycosis	1
Pyelonephritis Acute	1
Pseudomonas Infection	1
Oral Fungal Infection	1
CFS Virus Identified	1
Candidiasis	1
Total	60

154. A review of the Adverse Event Report further revealed the following additional 163 severe infections that occurred in patients taking Tysabri that could be opportunistic infections associated with severe immunosuppression, although additional information would be required to make that determination.

Infection	**Number Reported**
Pneumonia	29
Diarrhea	29
Fungal Infection	10
Kidney Infection	8
Herpes Simplex	8
Infection	7
Viral Infection	6
Herpes Zoster	5
Pneumonia Bacterial	4
Pericarditis	4
Respiratory Tract Infection	4
Gastroenteritis Viral	4
Bronchopneumonia	4
Stomatitis	3
Respiratory Tract Infection Viral	3
Lobar Pneumonia	3
Hepatitis	3
Escherichia Infection	3
Abscess Limb	2
Aphthous Stomatitis	2
Infectious Mononucleosis	2
Infected Cyst	2
Pneumonia Viral	2
Streptococcal Infection	1

Staphylococcal Infection	1
Staphylococcal Abscess	1
Septic Arthritis Staphylococcal	1
Purulent Discharge	1
Oral Infection	1
Meningitis Viral	1
Lower Respiratory Tract Infection	1
Herpes Virus Infection	1
Fungal Skin Infection	1
Febrile Infection	1
Eye Infection	1
Epstein-Barr Virus Test Positive	1
Epstein-Barr Virus Infection	1
Empyema	1
Arthritis Bacterial	1
Total	163

155. With respect to malignancies, six cases of malignant melanoma and at least two cases of lymphoma, which are associated with severe immunosuppression, appeared on the Adverse Event Report. In addition, the Adverse Event Report disclosed the following other reported malignancies: (i) eight reports of ovarian cancer; (ii) two reports each of the following malignancies: astrocytoma malignant, neoplasm malignant, metastases to lymph nodes, metastases to liver, lung neoplasm; and (iii) one report of each of the following malignancies: papillary thyroid cancer, metastatic malignant melanoma, metastases to skin, metastases to peritoneum, malignant pleural effusion, malignant neoplasm progression, gastric neoplasm, gastric cancer, endometrial cancer and colon cancer.

156. Moreover, a Professor of Neurology with expertise in immunology of the CNS as well as MS ("CS 7"), commented on the purported misdiagnosis of a Crohn's Disease patient who was diagnosed in July 2003 with malignant astrocytoma (brain cancer) and died in December 2003. According to CS 6, the misdiagnosis was highly suspicious. In this witness's opinion, a neuropathologist with even a few months training would not have misdiagnosed this patient. Similarly, according to a senior scientist at the National Institute of Health specializing

in the JC virus ("CS 8"), PML and astrocytoma are completely dissimilar and any neuropathologist with any skill would not have made this purported misdiagnosis.

157. According to CS 7, the neuropathologist who re-examined the case in March 2005 only needed to examine the CNS specimens from the Crohn's patient for about ten minutes before determining that it was PML rather than a malignant astrocytoma (brain cancer). CS 7 suggested that the purported misdiagnosis of the Crohn's Disease patient was the result of either an effort to conceal the true diagnosis or malpractice on the part of the neuropathologist because in CS 7's opinion, there was no way a competent neuropathologist would confuse PML with a brain cancer. Thus, CS 7 was concerned that there could be other similar incidents that had been concealed or misdiagnosed.

158. Given that Tysabri was removed from the market in February 2005 after one reported death from PML, had the proper diagnosis been made in December 2003 that this Crohn's Disease patient actually had PML, Tysabri would almost certainly not have received fast-track approval from the FDA and the FDA would have required the black-box warning Tysabri has today.

159. An August 29, 2005 *Wall Street Journal* article (the "August 29 WSJ Article") analyzing adverse events associated with Tysabri obtained from the FDA pursuant to a FOIA request similarly concluded that the FDA adverse event data contained "numerous" accounts of serious, opportunistic infections that ***"suggest again that the toll from Tysabri extends beyond PML."*** [Emphasis added].

160. According to the August 29 WSJ Article, at least seven non-PML deaths in patients taking Tysabri "appear[ed] to be related to immunosuppression." The August 29 WSJ Article further observed that one death resulted from pneumoncystis carinii pneumonia, an

infection that only patients with severely debilitated immune systems contract; another death was attributed to herpes encephalitis, a rare infection of the CNS; and four other deaths appeared to be caused by sepsis, an uncontrolled bacterial infection spreading throughout the body.

161. As discussed below, despite the numerous serious opportunistic infections that occurred during the Tysabri clinical trials, and the other numerous warnings discussed above, Defendants continued to report a stellar safety profile for Tysabri with purportedly only common, non-life threatening, treatable infections that occurred in the clinical trials and throughout the relevant period. Defendants also continually touted Tysabri as a blockbuster drug when, in fact, Defendants already knew of the serious side effects that resulted from Tysabri and thus, it would not be even close to a blockbuster drug.

VI. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD

162. As discussed above, Defendants knew, or recklessly disregarded, numerous facts known to them well before the Class Period began, and well before applying for, and receiving FDA approval, informing them that Tysabri was a highly immunosuppressive drug that would inevitably result in serious, sometimes life-threatening, opportunistic infections. Specifically, Defendants were aware of the following results and events that occurred prior to the beginning of the Class Period:

- **1992 - 2002** - Animal studies indicating that Tysabri effectively worked to turn off the immune system were conducted from at least 1992 to 2002 and the results of those studies were published during that time. Thus, the results of the animal studies were known to Defendants well before the Class Period and well before they applied for, and received approval of Tysabri in November 2004 (¶¶ 101-112);

- **1995 - January 2004** - Numerous serious opportunistic infections had occurred in patients taking Tysabri during the Defendants' Tysabri clinical trials. The infections were unblinded by January 2004, and thus, known to Defendants by at least January 2004, prior to submitting an application to the FDA for fast-track approval of Tysabri (¶¶ 87-95, 129-150);

- **<u>1995 - January 2004</u>** - Confidential sources intimately involved with the development and testing of Tysabri confirmed that Defendants knew that Tysabri was a highly dangerous drug, from at least 1995 through January 2004, well before the Class Period and well before they received FDA approval (¶¶ 143-150); and

- **<u>September 2004 - January 2005</u>** - Defendants attended scientific meetings prior to, and during the Class Period where top scientists in the field discussed the serious and inherent risks of Tysabri (¶ 118).

163. Notwithstanding the numerous warnings above concerning the serious risks associated with Tysabri, Defendants, throughout the Class Period continually touted Tysabri as the next "blockbuster drug" with a "reassuring safety profile" that would result in "4+ billion dollars" of additional revenue for Biogen and Elan. In this regard, Defendants made the following materially false and misleading statements and omissions to the investing public during the Class Period.

164. On February 18, 2004, the beginning of the Class Period, Defendants issued a press release (the "February 18, 2004 Press Release") communicating their "Intention to Submit Antegren® for Approval for Multiple Sclerosis Based on One-Year Data." The February 18, 2004 Press Release stated in relevant part:

> The decision to file a Biologics License Application (BLA) was made after discussions with the FDA of one-year data from the two ongoing two-year Phase III trials in MS. The companies are committed to completing the two-year trials. To protect the integrity of the trials, the companies are not disclosing the one-year data at this time.

165. Defendants reported that with respect to adverse events reported during Tysabri clinical trials that:

> In previous clinical trials, the following adverse events occurred more commonly with natalizumab when compared to placebo: headache, nausea, abdominal pain, infection, urinary tract infection, pharyngitis and rash. Serious adverse events have included infrequent hypersensitivity-like reactions.

166. In the February 18, 2004 Press Release, Defendants also described the Tysabri clinical trials as follows:

> The AFFIRM (natalizumab safety and efficacy in relapsing-remitting MS) trial is a two-year, randomized, multi-center, placebo-controlled, double-blind study of approximately 900 patients, evaluating the ability of natalizumab to slow the progression of disability in MS and reduce the rate of clinical relapses. The SENTINEL (safety and efficacy of natalizumab in combination with AVONEX® (Interferon beta-1a)) trial is a two-year, randomized, multi-center, placebo-controlled, double-blind study of approximately 1,200 patients with relapsing-remitting MS, evaluating the effect of the combination of natalizumab and AVONEX compared to treatment with AVONEX alone in slowing the progression of disability and reducing the rate of clinical relapses.
>
> Both studies have protocols that included a one-year analysis of the data. The primary endpoints for both Phase III two-year trials in MS are based on the Expanded Disability Status Scale (EDSS) and relapse rates. The pre-specified primary endpoint of the one year-analysis was relapse rates.

167. Moreover, in an article published by *Bloomberg* on February 18, 2004 (the "February 18, 2004 *Bloomberg* Article"), Biogen spokesperson Amy Brockelman, assured investors and analysts: "Based on our discussion, we believe that one-year data are sufficient for filing."

168. Moreover, as demonstrated in the February 18, 2004 *Bloomberg* Article, investors were convinced by Defendants' material misrepresentations that Tysabri would be highly profitable to the Company. For example, with respect to Biogen's announcement of its intention to seek fast-track approval of Tysabri, Richard Barnett, a Los Angeles-based fund manager for Northern Trust Corp. who purchased Biogen stock was quoted as follows: "***This event definitely removes some uncertainty from a potential blockbuster drug in the Biogen Idec pipeline. It pushes revenues and profit growth forward.***" [Emphasis added]. Moreover, John McCamant, editor of the Medical Technology Stock Letter in Berkeley, California commented on Tysabri's

safety as follows: "The Biogen Idec-Elan drug appears to be safer than some of its potential rivals."

169. Analysts also reacted to the Defendants' materially false and misleading statements. For example, in the February 18, 2004 *Bloomberg* Article, SG Cowen estimated Tysabri sales for MS "may eventually exceed $1 billion a year." Moreover, several analysts raised their recommendations and earnings estimates as follows:

- First Albany, A.G. Edwards and Deutsche Bank- "buy,"
- Wachovia Securities - "outperform" and raising price target to $60-$64 from $41-$46, commenting "[t]he planned mid-2004 filing is 9-12 months ahead of expectations and speaks to the robust efficacy and more manageable side effect profile of Antegren."
- UBS - raising price target from $60 to $70.
- RBC Capital Markets - Under the headline: "Antegren Flexes Blockbuster Potential," raising price target to $68.
- Cathay Financial - "outperform" and raising price target to $56 (from $50).

170. Following Defendants' affirmative misrepresentations, Biogen's stock price soared to close at $53.23 per share on February 18, 2004, up $8.85 per share, or 20.9%, from the previous day's closing price of $44.26, on trading volume of approximately 34.5 million shares, nearly nine times the average daily trading volume during the Class Period.

171. The same day, Defendant Rohn sold 25,000 shares of Biogen stock at artificially inflated prices, reaping approximately $1.3 million in proceeds.

172. The February 18, 2004 Press Release was materially false and misleading because, once Defendants chose to speak about the Company and success of Tysabri, they had a duty to speak fully and accurately concerning the true risks of Biogen's business, operations, performance and prospects and thus, the true risks of Tysabri. The statements identified above in

the February 18, 2004 Press Release were materially false and misleading at the time they were made because:

(a) Tysabri had serious, undisclosed side effects that were inherent in the nature of the drug and the way it worked to suppress the immune system, leaving patients vulnerable to life-threatening infections, including PML, pulmonary aspergillosis, pneumocystis carinii pneumonia, atypical mycobacterial infections and various herpes virus infections associated with immunosuppression;

(b) Tysabri's severe immunosuppressive effect was likely to, and did, cause a plethora of dangerous opportunistic infections;

(c) clinical trials of Tysabri failed to include the full range of medical tests necessary to timely detect symptoms of serious opportunistic infections, such as lumbar punctures, routine blood tests and neurological examinations;

(d) the one-year data from Tysabri clinical trials was not as successful as Defendants led investors to believe because it did not disclose that Tysabri had already caused serious opportunistic infections;

(e) the "severe adverse events" that occurred during the trials extended far beyond the purported "infrequent hypersensitivity-like reactions" or minor infections that Defendants disclosed;

(f) because of its substantial risks to patients, Tysabri would have a very limited use, in patients in the most advanced stages of MS where alternative treatments were unsuccessful, and thus the potential market for Tysabri was only

a fraction of the potential purported $4 billion MS market that Defendants represented and Tysabri would contribute only marginally to Biogen's earnings; and

(g) in light of the foregoing, Defendants' unqualified positive representations concerning Biogen's operations, business, performance, and prospects lacked any reasonable basis and were contradicted by facts known to, or recklessly disregarded by, Defendants.

173. On February 18, 2004 and February 19, 2004, Wachovia Securities Credit Suisse First Boston respectively upgraded Biogen to "Outperform," based upon "strong Antegren data" and the Company's decision to file for fast-track approval of Tysabri. In their February 18, 2004 research report, Wachovia analysts highlighted the following key points supporting the upgraded rating:

> * EARLY FILING INDICATIVE OF STRONG DATA. BIIB'S decision to file based on one year relapse data, rather than wait for the more commonly accepted two year EDSS score, implies a superior treatment experience with Antegren relative to current standard of care beta-interferons.
>
> * EXPECT SALES NEAR $1 BILLION IN 2008. We look for significant Antegren penetration in treatment naive patients as well as beta-interferon failures and patients rotating among currently approved therapies. We model total Antegren sales of $130 million, $353 million, $683 million and $941 million in 2005-2008.
>
> * BIIB'S ACCELERATING GROWTH TRENDS ARE AN ANOMALY IN LARGE CAP BIOTECH. With an Antegren launch in 2005, BIIB will be one of the few large cap biotechs with accelerating earnings trends over the next few years, which should place it in spotlight among investors looking for high growth opportunities among profitable biotechs.

174. Moreover, analysts continued to revise their ratings upward and increase earnings estimates. Specifically, on February 18, 2004 and February 19, 2004 respectively, the following analysts raised their estimates:

- **Wachovia –** analysts increased valuation of Biogen stock from $60 to $64 per share and 2005 earnings estimates from $1.72 per share to $1.80 per share based upon the expectation that "Antegren will likely take BIIBs current 12-14% growth rate to 20-24% in 2005-2008, yielding 2008 EPS of $2.94."
- **CSFB** - analysts upgraded Biogen to outperform and increased target stock price to $62 per share, stating "[W]hile opening up new opportunities to treat patients with earlier disease, keyed to Antegren's good safety, remarkable tolerability, and infrequent (once a month) dosing interval."
- **Piper Jaffray** - analysts raised rating of Biogen to "outperform" and increased the target stock price of the Company to $65 per share.

175. At the same time, Biogen shares continued to climb to close at $58.98 per share on February 19, 2004, up $5.75 per share, or 12.8%, from the previous day's closing price of $53.23, on trading volume of approximately 25.4 million shares, more than six and a half times the average daily trading volume during the Class Period.

176. On March 2, 2004, Defendants issued a press release announcing their fourth quarter and year-end 2004 financial results (the "March 2, 2004 Earnings Release") and reaffirming the Company's "Goal of Achieving an Average of 15 Percent Revenue Growth and 20 Percent Earnings Per Share." In the March 2, 2004 Earnings Release, Defendant Mullen touted the Company's success in developing new products, declaring:

> Since the completion of our merger late last year, we've had a string of successes in our product pipeline. Furthermore, the past four months of operating as one organization have confirmed the promise of our new company. Biogen Idec is well positioned to achieve our long-term goal of delivering an average of 15 percent top line and 20 percent bottom line growth through 2007.

177. With respect to Biogen's financial guidance, Defendants reported:

> The recent announcement by the Company, along with its partner, Elan Corporation plc (Elan), of their intention to submit with the U.S. Food and Drug Administration an application for the approval of ANTEGREN® (natalizumab) as a treatment for MS based on 1-year Phase III ***results further enhances the Company's confidence in its ability to achieve these previously stated earnings and revenue goals***. [Emphasis added].

178. Also on March 2, 2004, Defendants held a conference call with analysts (the "March 2, 2004 Conference Call"), in which each of the Individual Defendants participated. During the March 2, 2004 Conference Call, Defendants Mullen and Kellogg reiterated the Company's earlier earnings guidance. Defendant Mullen assured investors that the Company was "confident that Biogen Idec is well positioned to achieve our goal of delivering an average of 15% top-line and 20% bottom-line growth through 2007." Defendant Kellogg echoed those sentiments and promised substantial growth:

> The goals that we provided last June for the 4-year average growth rates are also in line. As we laid out, total revenues are targeted to grow 15% on average per year and adjusted EPS is targeted to grow 20% per year on average. If we meet these goals, Biogen Idec should reach a total revenue level of over $3.25 billion and an adjusted EPS above $2.60 in 2007. That's more than doubling our EPS in 4 years.

179. Moreover, Defendant Mullen reinforced investors' hopes with respect to Tysabri's future impact on the Company's revenue and earnings, stating that the Company's plan to file for fast-track approval "further supports our objectives of delivering 20% EPS growth over 4 years and so we are pretty excited about it."

180. Defendant Mullen went on to describe the market for Tysabri as "***huge***" and was quoted as follows:

> Now, I want to focus really on the current state of the MS market, I know a lot of people are beginning to think about that very carefully after this announcement two weeks ago. In the US, there is approximately 400 to 450,000 MS patients of which 300 to 350,000 in the relapsing forms, we consider that the eligible

> market, that market is slightly over half penetrated. That's about 180,000 patients in the US are on one of the interferons or Copaxone. There is more than 50,000 quitters, that number is hard to quantify but we think that's the right ballpark and there is about 10 to 15,000 new patients diagnosed annually. And when you think about the EU marketplace, you can pretty much just double all those numbers except the penetration is a little bit less***. So there is huge, there is still a huge unmet need out there***.
>
> * * *
>
> ***[W]e do believe that this innovative therapy will offer hope to a large number of patients and the market will grow significantly in the US and Europe.*** [Emphasis added]

181. Moreover, Defendant Adelman echoed Defendant Mullen's comments stating: "I think it's very important to remember that there is in our minds a very large currently unserved segment of the MS population for whom this will be a therapy that they can now consider." Later on during the March 2, 2004 Conference Call, Defendant Adelman reiterated his earlier guidance as to the predicted market for Tysabri and advised analysts that with respect to the market for Tysabri alone, versus being used in combination with Avonex®, that:

> First and foremost, we know that there is a significant population of patients out there falling out of existing therapies, because of either they don't want to give themselves an injection, they can't tolerate the adverse events associated with existing therapies, and, and/or they prefer the convenience of going to the doctor once a month to get an injection. So I think that's a group right there . . . We know that there are patients who have some degree of disease activity either as measured by relapse rate and/or MRI while they are on any of the current therapies, and that's why the clinical development program for this product includes not only a placebo-controlled trial as a standalone therapy, but includes study where we look at the efficacy of Antegren when added to patients already on interferon who still have some evidence of disease activity. ***So, I think it's going to be broadly applicable to the entire population of patients with MS who are or are not on therapy, who still have evidence of disease activity.*** [Emphasis added]

182. During the March 2, 2004 Conference Call, Defendant Rastetter praised the role of Tysabri in fulfilling Biogen's future goals and vision "to build Biogen Idec as one of the

world's premier biotech companies" stating that "the early filing of Antegren, of course, is another step in fulfilling this vision."

183. When asked by analyst Joel Sendek of Lazard about whether Biogen's earnings guidance included approval of Tysabri in 2005, Defendant Kellogg provided positive assurances as follows:

> We've always assumed that Antegren would be a product in our portfolio and it would be approvable and successful. So that's, you know, and as you get out to 2007, that's always been a base assumption that we've had . . . yes, the goals that we have as a company have always included Antegren as a successful product . . . .

184. Defendant Rohn repeated Defendant Kellogg's false assurance stating that "[o]bviously, great news on the earlier possibility for filing and hopefully approval. We'll be in the marketplace."

185. The statements identified in the March 2, 2004 Earnings Release and March 2, 2004 Conference Call were materially false and misleading for the reasons set forth in paragraph 172 above.

186. After the earnings announcement on March 2, 2004, Defendant Rohn profited from Biogen's artificially inflated stock price, selling 125,000 shares that day and reaping approximately $7 million in proceeds as a result of Defendants' materially false and misleading statements above.

187. The following day, on March 3, 2004, analysts continued to rally and upgrade their ratings and estimated earnings and stock price targets. Specifically, WR Hambrecht raised its target stock price for Biogen to $66 per share and reiterated its "buy" recommendation, commenting that "[w]ith Biogen on track to file the Antegren BLA in mid-04 based on 1-year data, BIIB has entered what we believe is a significant growth phase, driven by its 3rd ***potential***

blockbuster drug." [Emphasis added]. Similarly, SG Cowen commented that "[a]n early filing suggests compelling efficacy and ***positions Antegren to be a first-in-class blockbuster in MS."***

188. On March 10, 2004, Defendants filed Biogen's Annual Report on Form 10-K for the period ended December 31, 2003 (the "2003 10-K"), signed by Defendants Mullen, Kellogg and Rastetter. The 2003 10-K contained the same materially false and misleading statements as the February 18, 2004 Press Release with respect to the Tysabri clinical trials.

189. Moreover, Exhibits 31.1 and 31.2 to the 2003 10-K contained certifications signed by Defendants Mullen and Kellogg pursuant to section 302 of the Sarbanes Oxley Act of 2002 ("Sarbanes Oxley"), which stated that the Form 10-K did not contain any material misrepresentations and that the Company maintained adequate internal controls, as follows:

> SECTION 302 CEO CERTIFICATION
>
> I, James C. Mullen, certify that:
>
> 1. I have reviewed this annual report of Biogen Idec Inc.;
>
> 2. Based on my knowledge, ***this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;***
>
> 3. Based on my knowledge, the financial statements, and other financial information included in this report, ***fairly present in all material respects the financial condition, results of operations and cash flows of the registrant*** as of, and for, the periods presented in this report;
>
> 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
>
> a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, ***to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known***

to us by others within those entities, particularly during the period in which this report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2004

/s/ James C. Mullen

James C. Mullen
Chief Executive Officer and President

SECTION 302 CEO CERTIFICATION

I, Peter N. Kellogg, certify that:

1. I have reviewed this annual report of Biogen Idec Inc.;

2. Based on my knowledge, ***this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the***

circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, ***fairly present in all material respects the financial condition, results of operations and cash flows of the registrant*** as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, ***to ensure that material information relating to the registrant,*** including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2004

/s/ Peter N. Kellogg

Peter N. Kellogg
Executive Vice President, Finance and
Chief Financial Officer

190. Exhibit 32.1 to the 2003 Form 10-K also contained a certification signed by Defendants Mullen and Kellogg, pursuant to section 906 of Sarbanes Oxley, which stated that the 2003 Form 10-K did not contain any material misrepresentations, as follows:

SECTION 906 CEO/CFO CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) each of the undersigned officers of Biogen Idec Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report on Form 10-K for the year ended December 31, 2003 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 9, 2004 /s/ James C. Mullen

James C. Mullen
Chief Executive Officer and President

Dated: March 9, 2004 /s/ Peter N. Kellogg

Peter N. Kellogg
Executive Vice President, Finance and
Chief Financial Officer

191. With respect to Biogen's internal controls, the 2003 10-K further disclosed:

Item 9A. Controls and Procedures.

> We have carried out an evaluation, under the supervision and the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the fiscal year covered by this report. Based upon that evaluation, our principal executive officer and principal financial officer ***concluded that our disclosure controls and procedures are effective in providing reasonable assurance*** that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

192. On or about March 10, 2004, Defendants also issued Biogen's Annual Report for the fiscal year ended December 31, 2003 (the "2003 Annual Report"). The 2003 Annual Report contained essentially the same materially false and misleading statements regarding Tysabri and the Tysabri clinical trials as those contained in the February 18, 2004 Press Release.

193. The statements identified in the Biogen 2003 10-K and 2003 Annual Report were materially false and misleading for the reasons set forth in paragraph 172 above. In addition, the statements made in the 2003 10-K were materially misleading because: (i) Defendants lacked the necessary controls to ensure that adverse events were properly reported to the FDA in a timely manner; (ii) the Company violated Sarbanes Oxley, 18 U.S.C. § 1350, as adopted pursuant to § 302 and § 906, by issuing the false certifications, as stated above; and (iii) the Company violated Section 13(b)(2)(B) of the Exchange Act by misrepresenting that Biogen

maintained adequate internal controls, when, in fact, Biogen's controls were deficient, allowing Defendants to engage in the fraud alleged herein.

194. On March 10, 2004, CIBC issued a report projecting future revenues from Tysabri, based upon Defendants' materially false and misleading statements, as follows:

> We believe Antegren's efficacy, convenient dosing (a monthly IV infusion, compared with weekly or thrice-weekly IM or SC injections for interferon therapies), apparently low side effects, and novel mechanism of action, give it peak sales potential of approximately $1.7 billion in 2010.

195. On March 23, 2004, Defendants issued a press release announcing their intention to seek regulatory approval of Tysabri in Europe, and entitled, "Biogen Idec and Elan Announce Intention to Submit Antegren® for Approval for Multiple Sclerosis In Europe" (the "March 23, 2004 Press Release"). Defendants described the drug as follows:

> About ANTEGREN (natalizumab)
>
> Natalizumab, a humanized monoclonal antibody, is the first alpha-4 antagonist in the new SAM (selective adhesion molecule) inhibitor class. The drug was designed to selectively inhibit immune cells from leaving the bloodstream and to prevent these cells from migrating into chronically inflamed tissue as occurs in a variety of inflammatory diseases. To date, approximately 2,800 patients have received natalizumab in clinical studies. In previous clinical trials, the following adverse events occurred more commonly with natalizumab when compared to placebo: headache, nausea, abdominal pain, infection, urinary tract infection, pharyngitis and rash. ***Serious adverse events have included infrequent hypersensitivity-like reactions***. [Emphasis added].

196. On March 23, 2004, CIBC issued another report, praising Biogen and Elan on their progress towards getting approval of Tysabri, as follows:

> On 3/23 before the open, BIIB and its partner ELN announced their intention to submit Antegren to the EMEA (the European equivalent of the FDA) for approval in MS in the summer of 2004. We believe this is an incremental positive for BIIB.

> While BIIB and ELN have not revealed any of the one-year relapse data, we believe the decision to file in Europe provides additional validation of our thesis that the data show strong efficacy and safety.

197. Following Defendants' affirmative misrepresentations, Biogen shares rose to close at $54.65 per share on March 24, 2004, up $1.89 per share, or 3.6% from the previous day's closing price of $52.76.

198. The statements identified in the March 23, 2004 Press Release above were materially false and misleading for the reasons set forth in paragraph 172 above.

199. On April 30, 2004, Defendants issued their earnings report for the first quarter of 2004 (the "April 30, 2004 Earnings Release") declaring: "U.S. filing for ANTEGREN® (natalizumab) as a Treatment for Multiple Sclerosis (MS) On Track for Submission in the Second Quarter." Defendant James Mullen further encouraged investors as to the success of Tysabri stating, in relevant part:

> We've had an excellent start to the year. Both revenue and earnings results are up strongly. The U.S. filing of ANTEGREN by mid-year is on track. Our recent good news on ANTEGREN's accelerated timeline highlights one of the strategic benefits of the merger. With access to two large scale manufacturing facilities on both coasts, ***the Company is well-positioned to fulfill ANTEGREN's blockbuster potential.*** [Emphasis added]

200. In the April 30, 2004 Earnings Release, Defendant Rastetter echoed Defendant Mullen's sentiments about the Company's successes stating: "With three products in Phase III development ANTEGREN in MS and Crohn's Disease, BG-12 for psoriasis in Europe, and RITUXAN® (rituximab) in rheumatoid arthritis ***we have a robust pipeline that reaffirms our commitment to our corporate goal of average 15% revenue growth and 20% EPS growth through 2007***." [Emphasis added]

201. That same day, the Defendants held a conference call with analysts (the "April 30, 2004 Conference Call"), in which all of the Individual Defendants participated. During the April 30, 2004 Conference Call, Defendant Rastetter touted the Company's strong first quarter performance and the Company's "robust pipeline" as follows:

> In addition to a great quarter, most recently the great news on the accelerated timeline for ANTEGREN highlights one of the synergies of the merger . . . . So the good news on ANTEGREN further validates the strategic elegance of bringing the 2 companies together. With 3 products in Phase III development, ANTEGREN in MS and Crohn's disease, BG-12 for psoriasis in Europe, and RITUXAN in rheumatoid arthritis, ***we have a robust pipeline that reaffirms our commitment towards our corporate goal of averaging 15% revenue growth and 20% EPS growth in 2007***.

202. During the April 30, 2004 Conference Call, Defendant Kellogg reiterated earlier financial guidance concerning the Company's commitment to 15% to 20% revenue and earnings per share growth, and directly attributed that earlier guidance, in part, to the purported successful one-year data from the Tysabri clinical trials which supported estimated future revenue projections, as follows:

> First of all, the ANTEGREN news further supports our long-term goal of delivering 15% top line and 20% average EPS growth from 2003 to 2007, just as Bill and Jim mentioned.

203. With respect to questions concerning the Tysabri market, Defendant Rohn stated, in relevant part:

> Overall, we are very excited about the opportunity that ANTEGREN represents. Recently, there has been a lot of investor focus on this opportunity, so let me put it in perspective. ***We believe the potential MS market over the next few years will grow to $6 billion, approximately, up from about $3.6 billion today.*** We believe ANTEGREN will not only expand the market, but also capture a very significant share of the market. What will drive this growth? Well, simply innovation in the form of a new mechanism of action. It's been several years since the last meaningful therapy in MS was introduced, and untreated patients are ready for a new product . . . . ***By addressing this unmet need in the marketplace,***

> ***ANTEGREN will rejuvenate and expand the market*** by accessing those, approximately 100,000 patients worldwide that have failed current therapies.

204. Moreover, Defendant Adelman confirmed Defendant Rohn's earlier comments with respect to patients that have fallen out of current MS therapies, stating: "there is nothing that we would believe about the biology of those patients and the mechanism of action of ANTEGREN that would a priori make us believe they would be less likely to respond to ANTEGREN therapy, so I am comfortable that they represent an important pool of patients for whom ANTEGREN can make an important difference."

205. With respect to Biogen's seeking priority review from the FDA, Defendant Adelman assured investors that "we certainly do believe that we have good reason to ask for an accelerated review."

206. Upon the news, analysts, relying on Defendants' materially false and misleading statements, praised the Company and increased targets. Specifically, CSFB raised its twelve-month target stock price to $63 per share, stating: "***We continue to view Antegren as the key to BIIB's stock***." [Emphasis added]. Similarly, SG Cowen echoed CSFB, proclaiming: "Longer-term, BIIB stock performance will be tightly correlated with the commercial prospects of Antegren in MS." Likewise, A.G. Edwards maintained its buy rating and commented that "we believe the upcoming launch of Antegren for MS will secure solid growth for this company through the end of the decade."

207. Biogen shares rose further to close at $59.00 per share on April 30, 2004, up $1.99 per share, or 3.5%, from the previous day's closing price of $57.01, on trading volume of approximately 10.98 million shares, nearly three times the average daily trading volume during the Class Period.

208. The statements identified above in the April 30, 2004 Earnings Release and April 30, 2004 Conference Call above were materially false and misleading for the reasons set forth in paragraph 172 above. Moreover, the above statements were further materially false and misleading because Defendants' drug pipeline was not as "robust" as represented and Defendants did not, as they represented, have a "good reason to ask for accelerated review," given Tysabri's true, undisclosed immunosuppressive qualities and risk of life-threatening opportunistic infections.

209. On May 6, 2004, the Company filed its quarterly report on Form 10-Q for the quarter-ended March 31, 2004 (the "First Quarter 2004 10-Q"), signed by Defendant Kellogg. The First Quarter 2004 10-Q contained essentially the same false and misleading statements regarding the Company's internal controls and the same false and misleading Sarbanes Oxley certifications as contained in the 2003 10-K, signed by Defendants Mullen and Kellogg.

210. The statements identified in the First Quarter 2004 10-Q were materially false and misleading for the reasons set forth in paragraph 172 above.

211. Shortly after Defendants filed Biogen's First Quarter 2004 10-Q, on May 13, 2004, ING Financial Markets issued a research report entitled "Antegren on Track." In that report, ING analysts forecasted growth of the MS market from $3.5 billion to more than $6 billion by 2008 and forecasted Tysabri sales to reach $2.2 billion by 2008. That same day, Deutsche Bank issued a similar research report forecasting worldwide Tysabri sales of $2.3 billion by 2009. Moreover, when adding forecasted revenue from Crohn's patients on Tysabri, Deutsche Bank forecasted revenue from Tysabri in 2009 of $3.1 billion, "***which would make this therapy one of the largest-selling biologics on the market***." [Emphasis added]

212. On May 19, 2004, Prudential Equity Group issued a report praising the safety profile of Tysabri, further underscoring the importance to the public that Tysabri is not just effective, but safe, and evidencing the public misconception about the true risks of Tysabri. Specifically, the Prudential Equity report stated:

> ***The safe profile of Antegren is encouraging for multiple sclerosis.*** The presentation of the ENACT-2 data provided a first glimpse at the long-term safety of Antegren. ***The drug appears to have a clean safety profile*** which is not differentiated from placebo. This is important for the use of Antegren in multiple sclerosis (MS). Remember that Biogen is filing Antegren for use in MS based on phase II data and data from the 2-year studies has not yet been released. ***We were encouraged to see such a clean safety profile for Antegren***, which would be welcomed in the MS patient population that is characterized by drugs that are burdened by significant adverse events including infection and flu like symptoms. [Emphasis added]

213. Defendants issued a press release on May 25, 2004 (the "May 25, 2004 Press Release") announcing their submission "to the U.S. Food and Drug Administration (FDA) for the approval of ANTEGREN® (natalizumab) for the treatment of multiple sclerosis (MS)." In the May 25 Press Release, Defendant Burt Adelman praised the results from the Phase III clinical trials, as follows:

> Based on the one-year analysis from our Phase III studies, which include more than 2,100 patients, we believe that natalizumab has the potential to become an important new therapy for MS. Natalizumab's novel mechanism of action represents an innovative approach to treating MS.

214. In the May 25, 2004 Press Release, Lars Ekman, MD, Executive Vice President and President, Research & Development at Elan echoed Defendant Adelman's sentiments, stating:

> This submission represents ***a significant milestone for Elan and Biogen Idec and demonstrates our continued commitment to providing a new treatment option for the more than one million patients experiencing the debilitating effects of MS***. We look

> forward to working with the FDA throughout the review process to make natalizumab available to patients who may be in need. [Emphasis added].

215. By including Dr. Ekman's statements in the Company press release, Defendants have necessarily adopted his statements as their own.

216. Moreover, Defendants, in the May 25, 2004 Press Release, described the Tysabri clinical trials as follows:

> About the MS Clinical Trials for Antegren:
>
> The AFFIRM (natalizumab safety and efficacy in relapsing-remitting MS) trial is a two-year, randomized, multi-center, placebo-controlled, double-blind study of approximately 900 patients, evaluating the ability of natalizumab to slow the progression of disability in MS and reduce the rate of clinical relapses. The SENTINEL (safety and efficacy of natalizumab in combination with AVONEX® (Interferon beta-1a)) trial is a two-year, randomized, multi-center, placebo-controlled, double-blind study of approximately 1,200 patients with relapsing-remitting MS, evaluating the effect of the combination of natalizumab and AVONEX compared to treatment with AVONEX alone in slowing the progression of disability and reducing the rate of clinical relapses.
>
> Both study protocols provided for a one-year analysis of the data. The primary endpoints for both Phase III two-year trials in MS are based on the Expanded Disability Status Scale (EDSS) and relapse rates. The pre-specified primary endpoint of the one year-analysis was relapse rate.
>
> About ANTEGREN (natalizumab):
>
> Natalizumab, a humanized monoclonal antibody, is the first alpha-4 antagonist in the new selective adhesion molecule (SAM) inhibitor class. The drug is designed to inhibit the migration of immune cells into chronically inflamed tissue where they may cause or maintain inflammation. To date, approximately 2,800 patients have received natalizumab in clinical trials, and the safety profile continues to support further development. In placebo-controlled trials to date, in both Crohn's disease (CD) and MS, the most commonly reported adverse events in either group were headache, fatigue and nasopharyngitis.

217. The statements identified above in the May 25, 2004 Press Release were materially false and misleading for the reasons set forth in paragraph 172 above.

218. On June 2, 2004, Morgan Stanley issued a report under the headline "Antegren Will Drive Sustainable Bottom-Line Growth" (the "Morgan Stanley Report"). The Morgan Stanley Report hyped the importance of Tysabri to Biogen and MS patients, characterizing Tysabri as ***"one of the true potential blockbuster drugs in biotech"*** which Morgan Stanley ***"expect[s] [] to alter the treatment paradigm for MS."*** Furthermore, the Morgan Stanley Report declared: "***We expect rapid adoption of the drug and peak sales of at least $3 billion per year . . . . Antegren is the most important product to the Biogen Idec investment thesis.***" [Emphasis added]

219. On June 4, 2004, Defendants issued a press release informing the investing public of their submission of Tysabri to the European Medicines Agency for approval as a treatment for MS in Europe (the "June 4, 2004 Press Release"). In the June 4, 2004 Press Release, Defendant Burt Adelman remarked:

> Based on the promising results in previous clinical trials and the one-year analysis from our Phase III studies, we believe ***natalizumab has the potential to meet a significant unmet need for MS patients around the world***. Natalizumab's novel mechanism of action represents an innovative approach to treating MS. [Emphasis added]

220. Again, Defendants included, in the Company release, statements from Dr. Ekman, thereby adopting Dr. Ekman's statements, further assuring investors that Tysabri would be a great success:

> This submission represents a significant milestone for Elan and Biogen Idec and demonstrates our ongoing commitment to new therapies for MS patients. We will continue to work with European regulators during the review process to bring natalizumab to patients as quickly as possible.

221. With respect to the clinical trials and Tysabri, Defendants made the following materially misleading statements in the June 4, 2004 Press Release:

> About the MS Clinical Trials for ANTEGREN
>
> The AFFIRM (natalizumab safety and efficacy in relapsing-remitting MS) trial is a two-year, randomized, multi-center, placebo-controlled, double-blind study of approximately 900 patients, evaluating the ability of natalizumab to slow the progression of disability in MS and reduce the rate of clinical relapses. The SENTINEL (safety and efficacy of natalizumab in combination with AVONEX® (Interferon beta-1a)) trial is a two-year, randomized, multi-center, placebo-controlled, double-blind study of approximately 1,200 patients with relapsing-remitting MS, evaluating the effect of the combination of natalizumab and AVONEX compared to treatment with AVONEX alone in slowing the progression of disability and reducing the rate of clinical relapses. Both study protocols provided for a one-year analysis of the data. The primary endpoints for both Phase III two-year trials in MS are based on the Expanded Disability Status Scale (EDSS) and relapse rate. The pre-specified primary endpoint of the one-year analysis was relapse rate.
>
> About ANTEGREN (natalizumab)
>
> Natalizumab, a humanized monoclonal antibody, is the first alpha-4 antagonist in the new selective adhesion molecule (SAM) inhibitor class. The drug is designed to inhibit the migration of immune cells into chronically inflamed tissue where they may cause or maintain inflammation. To date, approximately 2,800 patients have received natalizumab in clinical trials, and the safety profile continues to support further development. In placebo-controlled trials to date, in both Crohn's disease (CD) and MS, the most commonly reported adverse events in either group were headache, fatigue and nasopharyngitis.

222. The statements identified above in the June 4, 2004 Press Release were materially false and misleading for the reasons set forth in paragraph 172 above.

223. On June 28, 2004, Defendants issued a press release entitled, "FDA Designates Antegren Biologics License Application for Priority Review as a Treatment for Multiple

Sclerosis; Application Under Accelerated Approval Guidelines" (the "June 28, 2004 Press Release"). In the June 28, 2004 Press Release, Defendant Burt Adelman was quoted as saying:

> We are pleased that the FDA has designated natalizumab for Priority Review. We look forward to continuing to work with the FDA throughout the review process to provide this potential new therapeutic to patients with MS.

224. Defendants included the following materially false and misleading statement from Dr. Ekman of Elan in the June 28, 2004 Press Release:

> The Priority Review designation underscores the significant unmet medical need in the area of MS. We believe natalizumab will offer a new approach to treating MS and will bring hope to patients living with this disease.

225. In the June 28, 2004 Press Release, Defendants also described Antegren and its clinical trials as follows:

> About the MS Clinical Trials for ANTEGREN
>
> The AFFIRM (natalizumab safety and efficacy in relapsing-remitting MS) trial is a two-year, randomized, multi-center, placebo-controlled, double-blind study of approximately 900 patients, evaluating the ability of natalizumab to slow the progression of disability in MS and reduce the rate of clinical relapses.
>
> The SENTINEL (safety and efficacy of natalizumab in combination with AVONEX® (Interferon beta-1a)) trial is a two-year, randomized, multi-center, placebo-controlled, double-blind study of approximately 1,200 patients with relapsing-remitting MS, evaluating the effect of the combination of natalizumab and AVONEX compared to treatment with AVONEX alone in slowing the progression of disability and reducing the rate of clinical relapses. Both study protocols provided for a one-year analysis of the data. The primary endpoints for both Phase III two-year trials in MS are based on the Expanded Disability Status Scale (EDSS) and relapse rate. The pre-specified primary endpoint of the one-year analysis was relapse rate.
>
> About ANTEGREN (natalizumab)

> Natalizumab, a humanized monoclonal antibody, is the first alpha-4 antagonist in the new selective adhesion molecule (SAM) inhibitor class. The drug is designed to inhibit the migration of immune cells into tissues where they may cause or maintain inflammation. To date, approximately 2,800 patients have received natalizumab in clinical trials, and the safety profile continues to support further development. In placebo-controlled trials to date, in both Crohn's disease (CD) and MS, the most commonly reported adverse events in either group were headache, fatigue and nasopharyngitis.

226. Analysts reacted positively to Defendants' affirmative statements regarding Tysabri. On June 28, 2004, JP Morgan reiterated its overweight rating, stating: "[w]e believe the anticipation of the Antegren data will be a key driver of the stock over the next 6 months. Overweight rating reiterated." Similarly, Morgan Stanley issued a report that same day declaring: "We remain enthusiastic about Antegren in multiple sclerosis (MS), and this announcement bolsters our opinion that FDA approval could occur later this year . . . we continue to have high expectations for the regulatory and commercial success of Antegren." Cathay Financial upgraded their rating of Biogen to outperformed and raised its one-year price target to $72 per share (up from $60 per share).

227. The statements identified above in the June 28, 2004 Press Release were materially false and misleading for the reasons set forth in paragraph 172 above.

228. Upon the announcement, however, Defendant Adelman profited from Biogen's artificially inflated stock price, dumping 12,593 shares that day and reaping approximately $800,000 in proceeds as a result of Defendants' materially false and misleading statements.

229. The next day, on June 29, 2004, CIBC World Markets issued a report commenting on the impressive safety profile of Tysabri as follows: "We believe a superior side-effect profile and dosing convenience could make it the drug of choice for MS." That same day, Piper Jaffray issued a report rating Biogen "outperform" and raising its 12-18 month target stock

price to $80 per share to "reflect anticipation of positive news flow related to Antegren leading up to approval in late '04, followed by a strong commercial launch." Previous figures were set at $65. On June 30, 2004, Jefferies issued a report reiterating raising its "12 to 18-month price target to $62 from $50."

230. On July 26, 2004, Defendants issued a press release announcing that the FDA had accepted its Biologics License Application (BLA) for Antegren (the "July 26, 2004 Press Release"). In the July 26, 2004 Press Release, Defendants described Tysabri as follows:

> About ANTEGREN (natalizumab)
>
> Natalizumab, a humanized monoclonal antibody, is the first alpha-4 antagonist in the new selective adhesion molecule (SAM) inhibitor class. It is designed to inhibit the migration of immune cells into tissues where they may cause or maintain inflammation. To date, approximately 2,800 patients have received natalizumab in clinical trials, and the safety profile continues to support further development. In placebo-controlled trials to date, in both Crohn's disease (CD) and MS, the most commonly reported adverse events in either group were headache, fatigue and nasopharyngitis.

231. The statements identified above in the July 26, 2004 Press Release were materially false and misleading for the reasons set forth in paragraph 172 above.

232. On July 28, 2004, Biogen released its second quarter results (the "July 28, 2004 Earnings Release"). Defendants touted the Company's progress in obtaining fast-track approval of Tysabri. Specifically, Defendant Mullen stated, in relevant part:

> With the timeline of ANTEGREN accelerated by more than a year in MS, much of the energy of the organization is focused on preparing for launches in the U.S. and Europe. Together with our partner, Elan, we have made significant strides this quarter in the regulatory arena, as well as manufacturing and commercial preparation.

233. Defendants also held a conference call with analysts on July 28, 2004 in which each of the Individual Defendants participated. During the call, Defendant Mullen repeated

earlier guidance stating: "The acceleration of Antegren timeline further supports our goal of delivering an average 15% top-line and 20% bottom-line growth through 2007."

234. In the July 28, 2004 Earnings Release, Defendant Mullen touted Tysabri as the Company's next "blockbuster" drug, stating:

> Our commercial efforts on Antegren are focused on four key issues for a successful launch: reimbursement issues, the IV capabilities and capacities by neurologists, adding to sales force capacity, and the synchronizing with Elan. We and our partner Elan have been meeting regularly to formulate the launch plan. Kelly Martin and I are in frequent communication on a variety of issues. ***We are convinced of Antegren's blockbuster potential.*** [Emphasis added]

235. Defendant Rohn echoed Defendant Mullen's assurances to investors about the purported huge market for Tysabri stating:

> ***We are convinced of Antegren's blockbuster potential*** . . . . We believe the potential MS market over the next few years will grow to roughly $6 billion, up from $3.6 billion today, ***and we believe Antegren will not only expand the market but also capture a lion's share of the market.*** [Emphasis added]

236. During the July 28, 2004 Conference Call, Defendant Rastetter praised Biogen's ability to get Tysabri to market early and reiterated the Company's goal "for 50% of our pipeline to be generated from in-licenses opportunities by 2010" and touted its current drug pipeline, stating "[w]ith three products in Phase III development, Antegren in MS and Crohn's disease, BG-12 for psoriasis in Europe and Rituxan in rheumatoid arthritis, ***we have a robust pipeline that reaffirms our commitment to our corporate goal of averaging 15% revenue growth and 20% EPS growth through 2007."*** [Emphasis added]

237. When questioned during the July 28, 2004 Conference Call about Tysabri used in combination with other MS therapies, Defendant Adelman responded: "Antegren will be an important therapy for ***all*** patients with MS and obviously for patients currently on therapy who are not experiencing an adequate clinical response."

238. When asked about the potential likelihood of a "rebound" should a patient discontinue Tysabri therapy, Defendant Adelman responded: "there is no evidence that Antegren is associated with accelerated disease activation or relapse as we've seen with other potential targeted therapies to lymphocyte trafficking and you know, we have a huge safety database and theses issues have not come up in conversation, you know, with any regulatory authority."

239. Defendant Adelman's statement regarding the potential for rebound disease were false. Indeed, as discussed in paragraph 108 above, a study ***funded by Elan***, published in August 1999, concluded that there was a "possibility that there may be a rebound increase in the relapse rate after stopping treatment [of Tysabri] . . . ." Moreover, a subsequent study in 2001 ***co-authored by Dr. Cheryl Nickerson-Nutter, a Biogen researcher*** (¶¶ 109-110 above), found strong evidence that Tysabri treatment "***exacerbated relapses***." As explained above, patients on Tysabri who discontinued treatment may develop "rebound disease" in which their MS progresses at a much faster pace as if to catch up to the point where the disease would have progressed, absent the Tysabri.

240. Meanwhile, analysts continued to emphasize the importance of Tysabri to Biogen's bottom line. For example, in a July 28, 2004 report, entitled "The BIIB Story Is All About Antegren," SG Cowen commented that "[w]hile Biogen Idec's existing products appear capable of driving modest growth, ***much of the company's future success lies with Antegren***." Similarly, that same day, Morgan Stanley issued a report opining that "***[w]e regard Antegren as one of the most important biotech products currently in development***, and we believe that the Street does not fully appreciate the product potential and/or overestimates the threat of Avonex erosion to the bottom line."

241. The statements identified above in the July 28, 2004 Earnings Release and July 28, 2004 Conference Call were materially false and misleading for the reasons set forth in paragraph 172 above. The above statements were also in stark contrast to the research conducted by Dr. Miller, discussed in paragraphs 109-110 above.

242. On August 9, 2004, the Company filed its quarterly report on Form 10-Q for the period ended June 30, 2004 (the "Second Quarter 2004 10-Q"), signed by Defendant Kellogg. The Second Quarter 2004 10-Q contained essentially the same false and misleading statements regarding the Company's internal controls and the same false and misleading Sarbanes-Oxley certifications as contained in the 2003 10-K, signed by Defendants Mullen and Kellogg.

243. The statements identified above in the Second Quarter 2004 10-Q were materially false and misleading for the reasons set forth in paragraph 172 above.

244. On August 17, 2004, the Company issued a press release announcing an "Update on Global Filings and Data Release for ANTEGREN® for Multiple Sclerosis" (the "August 17, 2004 Press Release"). The August 17, 2004 Press Release described Tysabri as follows:

> Natalizumab, a humanized monoclonal antibody, is the first alpha-4 antagonist in the new selective adhesion molecule (SAM) inhibitor class. It is designed to inhibit the migration of immune cells into tissues where they may cause or maintain inflammation. To date, approximately 2,800 patients have received natalizumab in clinical trials, and the safety profile continues to support further development. In placebo-controlled trials to date, in both Crohn's disease (CD) and MS, the most commonly reported adverse events in either group were headache, fatigue and nasopharyngitis.

245. The statements identified above in the August 17, 2004 Press Release were materially false and misleading for the reasons set forth in paragraph 172 above.

246. Biogen presented at a healthcare conference with Thomas Weisel Partners on September 8, 2004 (the "September 8, 2004 Healthcare Conference"). During the September 8, 2004 Healthcare Conference, Christina Dillon, Biogen's Senior Manager of Investor Relations,

presented the data from Tysabri clinical trials and essentially repeated the same false and misleading statements with respect to the Company's growth estimates, the Tysabri clinical trials and the potential Tysabri market, as contained in the June 28, 2004 Press Release. During the presentation, Defendants also represented that "***Antegren will probably become first line therapy*** and then the opportunity is for those that have breakthrough disease." [Emphasis added]

247. On September 23, 2004, Citigroup increased the target price for Biogen stock to $65 per share, explaining "we believe BIIB should trade at a premium to the large-cap biotech group given the prospects for Antegren."

248. The next day, September 24, 2004, SG Cowen issued a report under the headline, "Management Exudes Confidence in Antegren" announcing that "[m]anagement expressed much confidence in the regulatory and commercial prospects for Antegren." According to SG Cowen, "***much of the company's future success lies with Antegren.***" Thus, based upon Defendants' materially false and misleading statements, SC Cowen predicted that "***[t]he early filings suggests compelling efficacy and positions Antegren to be a first-in-class blockbuster in MS with market potential of $3B+.***" [Emphasis added]

249. On October 27, 2004, Biogen released its third-quarter earnings for the period ended September 30, 2004 (the "October 27, 2004 Earnings Release"). In the October 27, 2004 Earnings Release, Defendant Mullen applauded the Company's successes as follows:

> Since we completed our merger transaction approximately one year ago, Biogen Idec has delivered on its promise. I applaud the organization for the smooth and rapid integration. We've hit our major financial goals, the pipeline has advanced both through in-house efforts and business development deals, and we are on the verge of launching our next product.

250. Defendants also held a conference call with analysts on October 27, 2004, in which all of the Individual Defendants participated (the "October 27, 2004 Conference Call").

During the call, Defendant Kellogg reiterated the same financial guidance with respect to the Company's goal of 15% - 20% growth through 2007 and reminded analysts that "the most important metric for next year will be the ANTEGREN trajectory . . . ." In conclusion, Defendant Kellogg praised Biogen's success stating, "this is a very exciting time for the organization as we prepare for the launch of ANTEGREN. We are financially and operationally strong, and we are very ready to execute on this great opportunity."

251. During the October 27, 2004 Conference Call, Defendant Adelman hyped the success of Tysabri and assured investors that "[o]ur goal is to provide unfettered access to patients for infusions" and that Defendants were "***convinced of ANTEGREN'S blockbuster potential.***" [Emphasis added]. Moreover, Defendant Adelman rallied investors' hopes with respect to the Tysabri market as follows:

> Overall, we are very excited about the opportunity that ANTEGREN represents. With the introduction of ANTEGREN, we believe the potential MS market over the next few years will grow to approximately $6 billion, up from about $4 billion today. ***ANTEGREN should expand the market and become the number 1 therapy for MS.*** [Emphasis added]

252. When questioned about neurologists' concern for the safety of Tysabri, given the limited available data, the following exchange took place:

> **Adam Walsh** (Jefferies): In speaking with neurologists ahead of the ANTEGREN launch, some of them suggested to us that data of EDSS and long-term safety data might be needed to really galvanize clinical opinion behind the drug. Is this consistent with your own pre-market launch research here and do you think that you'll have adequate long-term safety data at launch to satisfy the majority of prescribing physicians?"
>
> **Defendant Mullen:** ***[W]e think that the 1-year data, which is going to be the relapse rate, is a sufficient basis for approval.*** Certainly the FDA believes that. And I believe as you saw in the Phase II trial results and those compelling results in the Phase II, that we believe that that's sufficient. Now as a practical matter, the long-term safety data, you only get long-term safety data with

> long-term use, so every product coming to the market really faces that. ANTEGREN has had probably more clinical use coming to this market than any other product that I've seen launch recently into these kind of markets . . . In terms of the 2-year data, the 2-year data really isn't going to be that far behind the 1-year data. We don't know what it's going to say yet, but I think as everybody knows and I'll remind everybody, the primary endpoint for the w-year data is the EDSS . . . . We certainly hope that that's going to be consistent with what we saw for the relapse data, ***but I believe that that data is sufficiently exciting that it is not going to be large barrier to use*** . . . .
>
> **Defendant Adelman**: I would just agree and reiterate the comments that Jim made. I mean this drug has seen many, many, many patients. So at the time of approval, there will be a large and deep safety database, with patients having being [sic] on drug for an extended period of time. So I don't think that there'll be a problem explaining to patients and physicians what the safety profile of this drug looks like.

253. Again, analysts reiterated how critical Tysabri was to Biogen's future growth. Specifically, Morgan Stanley stated, in an October 27, 2004 report, that "[w]e consider Antegren the key driver for the stock," predicting an increase in Biogen's stock price in November 2004 if Tysabri was approved.

254. The statements identified above in the September 8, 2004 Healthcare Conference, October 27, 2004 Earnings Release and during the October 27, 2004 Conference Call were materially false and misleading for the reasons set forth in paragraph 172 above.

255. The next day, on October 28, 2004, CIBC World Markets issued a report reemphasizing the market's view, based upon Defendants' materially false and misleading statements alleged herein, that Tysabri would be a blockbuster drug:

> We believe Antegren will be a blockbuster new treatment for MS and Crohn's disease. We forecast peak sales potential for Antegren of approximately $3 billion, based on what we believe to be conservative market penetration assumptions in these indications.

256. On November 3, 2004, Morgan Stanley issued a report an anticipating of FDA approval later that month, repeating its view that "***we believe Antegren will be a blockbuster drug, driving long-term BIIB returns***." [Emphasis added].

257. The next day, Bear Stearns praised Tysabri, declaring: "[w]e believe Antegren will transform BIIB into a growth leader."

258. On November 8, 2004, Biogen and Elan issued a joint press release entitled "Antegren One-Year Data From Phase III Affirm Study Showed Compelling Results in Meeting Primary Endpoint in Multiple Sclerosis" (the "November 8, 2004 Press Release"). According to the November 8, 2004 Press Release, Phase III of the Tysabri clinical trials "met the primary endpoint of clinical relapse rate reduction. In this international study of 942 patients with relapsing-remitting multiple sclerosis (RRMS), natalizumab reduced the rate of relapses by 66 percent compared to placebo, a statistically significant result. All secondary endpoints were also met."

259. In the November 8, 2004 Press Release, Defendants made the following materially misleading statements with regard to adverse events that occurred during the Tysabri clinical trials:

> Adverse events occurring in at least 5 percent of natalizumab-treated patients that were 2 percent more common than in placebo-treated patients included headache, fatigue and arthralgia. The overall incidence of infection was similar between the groups. Serious infections occurred in 1 percent of placebo-treated patients and 2 percent of natalizumab-treated patients. Serious hypersensitivity-like reactions occurred in approximately 1 percent of natalizumab-treated patients.

260. Defendant Adelman, touted the purported success of Tysabri in the Phase III MS trials in the November 8, 2004 Press Release as follows:

> These data demonstrate that natalizumab dramatically reduced the rate of relapses at one year. We believe natalizumab, with its

> novel mechanism of action, has the potential to be a significant step forward in the treatment of MS.

261. Dr. Lars Ekman of Elan reiterated Defendant Adelman's comments, praising Tysabri's success and future prospects, as follows:

> Natalizumab has the potential to make a real difference in the lives of MS patients. We are working closely with regulatory authorities to make natalizumab available to patients in need as soon as we can.

262. With respect to the clinical trials, the November 8, 2004 Press Release misleadingly described the trials as follows:

> The AFFIRM trial is a two-year, randomized, multi-center, placebo-controlled, double-blind study of 942 patients evaluating the effect of natalizumab monotherapy on the progression of disability in MS and the rate of clinical relapses. Secondary endpoints at one year included the number of new or newly enlarging T2-hyperintense lesions, the number of gadolinium-enhancing lesions and the proportion of patients who were relapse free. To enroll, patients had to be diagnosed with a relapsing form of MS and had to have experienced at least one relapse in the previous year. Patients were randomized to receive a 300 mg IV infusion of natalizumab (n=627) or placebo (n=315) once a month.
>
> * * *
>
> A second Phase III trial, SENTINEL, is a two-year randomized, multi-center, placebo-controlled, double-blind study of approximately 1,200 patients with relapsing-remitting MS, evaluating the effect of the combination of natalizumab and AVONEX® (Interferon beta-1a) compared with AVONEX alone on the progression of disability and the rate of clinical relapses.

263. The November 8, 2004 Press Release went on to describe Tysabri as follows:

> About ANTEGREN (natalizumab):
>
> Natalizumab, a humanized monoclonal antibody, is the first alpha-4 integrin antagonist in the new selective adhesion molecule (SAM) inhibitor class.

> It is designed to inhibit the migration of immune cells into tissues where they may cause or maintain inflammation. To date, over 2,800 patients have received natalizumab in clinical trials.

264. That same day, Defendants issued Biogen's quarterly report on Form 10-Q for the third quarter ended September 30, 2004, signed by Defendant Kellogg (the "Third Quarter 2004 10-Q"). The Third Quarter 2004 10-Q contained essentially the same false and misleading statements regarding the Company's internal controls and the same false and misleading Sarbanes-Oxley certifications signed by Defendants Mullen and Kellogg, as contained in the 2003 10-K.

265. Upon Defendants' positive statements, on November 8, 2004, analysts reiterated their expectations for Tysabri to become a blockbuster drug. Deutsche Bank issued a report announcing "1-year AFFIRM results support Antegren as blockbuster prospect." SG Cowen reported "Antegren Clearly A Superior Drug For MS." CSFB proclaimed: "These data greatly exceeded Wall Street expectations and could support rapid evolution of Antegren as the first-line standard of care agent in relapsing-remitting MS."

266. JP Morgan also issued a report praising Tysabri and its anticipated success as follows:

> [w]e Think Antegren Represent Biotech's Next Significant Blockbuster . . . . Given that this data appears to demonstrate some of the best results ever seen in the treatment of RRMS, we expect Antegren to rapidly ascend the market share rankings even with some of the execution hurdles in front of a successful launch . . . . ***Antegren might now represent the most efficacious and least toxic therapy to treat RRMS***. We are forecasting $350 million in 2005 sales. [Emphasis added]

267. The statements identified above in the November 8, 2004 Press Release and the Third Quarter 2004 10-Q were materially false and misleading for the reasons set forth in paragraph 172 above.

268. On November 17, 2004, Defendant Rohn made a presentation at a Credit Suisse First Boston Healthcare Conference, reiterating the Company's prior financial guidance of 15%-20% growth and emphasizing that "reinvesting in the R&D arena to drive that [drug] pipeline forward, [ ] is obviously so critical to the future of growth and success of an enterprise such as Biogen Idec" (the "November 17, 2004 Healthcare Conference"). Moreover, during the November 17, 2004 Healthcare Conference, Defendant Rohn repeated similar materially false and misleading statements with respect to Tysabri and the results of the Phase III Tysabri MS clinical trials and the potential market for Tysabri, as those contained in the November 8, 2004 Press Release.

269. Following Biogen's announcement touting the success of the one-year data from Phase III of the Affirm Study, on November 18, 2004, Prudential Equity Group issued a report proclaiming that the data presented in the Affirm trial "bodes well for the drug's efficacy. In addition, it appears as though the safety profile of the drug is clean and limited to adverse events such as fatigue, headache and arthralgia…. This data sets the tone for positioning of Antegren as a new approach to the management of MS with better efficacy, fewer side effects, enhanced convenience, and the possibility of combination therapy leading to an improved quality of life for patients with MS."

270. A few days later, on November 22, 2004, CIBC World Markets upgraded Biogen to Sector Outperformer based upon its "Valuation and Antegren Expectations."

271. On November 23, 2004, Defendants issued a press release entitled, "FDA Grants Accelerated Approval of Tysabri® Formerly ANTEGREN®, for the Treatment of Multiple Sclerosis" (the "November 23, 2004 Press Release"). In the November 23, 2004 Press Release, Defendants praised the Company's success stating "[a]pproval of TYSABRI Marks a Major

Advancement in the Treatment of MS Phase III Trials at One Year Demonstrate New Level of Efficacy — 66% Reduction in Rate of Relapses Seen in AFFIRM Monotherapy Trial."

272. In the November 23, 2004 Press Release, Defendant Mullen was quoted as saying:

> Tysabri is a powerful and innovative therapy that offers new hope for hundreds of thousands of people living with MS. ***We believe Tysabri will revolutionize the treatment of MS and become the leading choice for patients and physicians***. [Emphasis added]

273. Kelly Martin, Elan's CEO echoed Defendant Mullen's sentiments, stating: "***Tysabri is a significant breakthrough for patients with MS***. The approval of Tysabri, with its unique mechanism of action and new level of efficacy, has the potential to make a genuine difference in the lives of patients and families who struggle with the debilitating effects of this disease."

274. The November 23, 2004 Press Release provided an identical misleading description of the two Tysabri clinical trials as was disclosed in earlier press releases, including, among others, the November 8, 2004 Press Release, the July 26, 2004 Earnings Release, the June 28, 2004 Press Release, the June 4, 2004 Press Release and the May 25, 2004 Press Release.

275. The November 23, 2004 Press Release also discussed the safety profile of Tysabri as follows:

> **Safety**
>
> Common adverse events associated with TYSABRI include headache, fatigue, urinary tract infection, depression, lower respiratory tract infection, joint pain and abdominal discomfort. The rate of infection in both studies was approximately one per patient-year in both TYSABRI-treated patients and placebo-treated patients.
>
> Serious infections occurred in 1.3 percent of placebo-treated patients and 2.1 percent of TYSABRI-treated patients. Serious infections included bacterial infections such as pneumonia and

urinary tract infection, which responded appropriately to antibiotics. TYSABRI has been associated with hypersensitivity reactions, including serious systemic reactions, which occurred at an incidence of less than 1 percent of patients.

276. The Tysabri package insert that was provided to patients taking Tysabri made no mention of how severely immunosuppressive Tysabri really was. For example, the Tysabri package insert contained the following disclosures:

PRECAUTIONS

Immunosuppression

In Studies 1 and 2, concomitant treatment of relapses with a short course of corticosteroids was not associated with an increased rate of infection. The safety and efficacy of TYSABRI® in combination with other immunosuppressive agents have not been evaluated. Patients receiving these agents should not receive concurrent therapy with TYSABRI ® because of the possibility of increased risk of infections. (emphasis added).

* * *

ADVERSE REACTIONS

General

The most frequently reported serious adverse reactions with TYSABRI® were infections (2.1% versus 1.3% in placebo, including pneumonia [0.6%]), hypersensitivity reactions (1.3%, including anaphylaxis/anaphylactoid reaction [0.8%]), depression (.08%, including suicidal ideation [0.5%]), and cholelithiasis (0.8%).

277. Similarly, in Table 3 of the Tysabri package insert, Defendants reported infections such as urinary tract infections and lower respiratory tract infections, but made no mention of serious opportunistic infections that had occurred during clinical trials, such as pneumocystis carinii pneumonia, atypical mycobacterial infections or herpes encephalitis or herpes infections.

278. In a November 23, 2004 research report, JP Morgan again applauded the positive one-year data from the Affirm trial declaring that Tysabri was "poised to rapidly become Biogen

Idec's next blockbuster." JP Morgan predicted: "Biogen Idec's launch of Tysabri into the multiple sclerosis (MS) marketplace will represent a true change in how patients with relapsing remitting MS are treated." With respect to the side effects associated with Tysabri, JP Morgan stated that the "Lack of Significant Side Effects Will Be a Key Attribute" and that JP Morgan expected the "Approval of Tysabri to Transform the MS Playing Field."

279. The statements identified above in the November 17, 2004 Healthcare Conference and in the November 23, 2004 Press Release and Tysabri package insert were materially false and misleading for the reasons set forth in paragraph 172 above. Moreover, Defendants' statements were further materially false and misleading because Defendants had no reasonable basis for claiming that the potential market for MS would grow "***substantially***."

280. On November 24, 2004, Elan and Biogen held a joint conference call with analysts, specifically to discuss the recent FDA approval of Tysabri (the "Joint November 24, 2004 Conference Call"). During the Joint November 24, 2004 Conference Call, Defendant Mullen, Biogen's CEO, described Tysabri as follows:

> This is a great day for people living with MS. TYSABRI is the ***first major advance in nearly a decade, we expect, that it will revolutionize the treatment for multiple sclerosis.*** This innovation is clearly a breakthrough therapy for patients suffering with MS.
>
> * * *
>
> We feel strongly that TYSABRI is the most powerful treatment ever developed for MS and will raise the efficacy bar in the treatment of MS. The magnitude of the effect for TYSABRI in relapses and placebo control trials is twice that achieved in pivotal trials of current therapies . . . . ***We certainly believe that TYSABRI will move quickly in the first line therapy and become the number one MS product worldwide.***

281. With respect to the label, Dr. Gordon S. Francis, M.D., Vice President of Neurology at Elan, stated: The FDA gave us the broadest possible label, there were no restriction, they specifically said it could be used as monotherapy or as add-on therapy."

282. During the Joint November 24, 2004 Conference Call, Elan's Vice President also reassured the public about the safely of Tysabri:

> I think that's in addition to the very strong efficacy result that were just described and as important is that ***TYSABRI appears to be safe and well tolerated and have a reassuring safety profile*** . . . . The AFFIRM study fielded the bulk of the safety information in the package insert and the safety profile in SENTINEL was similar.

283. Robert Hamm, Biogen's Senior Vice President of Immunology Business Unit, in describing the commercialization of Tysabri, stated that he expected Tysabri would be used as treatment in monotherapy or in combination, as follows:

> The SENTINEL trial as you referred demonstrates the benefit of adding TYSABRI, a new therapy with the different mechanism of action onto the current standard care, which is AVONEX. ***We believe this will result in expanding the market.*** There are approximately 350,000 patients with relapsing forms of MS in the US today. About 190,000 patients on therapy, which represents a penetration of approximately 55%. But after a decade of available treatment, many patients remain untreated and that's due to the high unmet need, which means the current therapies are partially effective, require frequent injections and many patients are intolerant of the idea effect profile. ***TYSABRI meets these needs with a new way to fight MS with great efficacy data, dosing every 4 weeks, and with a good tolerability and safety profile. We expect the MS market to grow from 4 billion today to over 6 billion driven by the market expansion.*** This growth comes from bringing back the quitters. We estimate that over 50,000 patients in the US have left therapy, and another 50,000 worldwide. ***TYSABRI will be first-line for new patients and TYSABRI will pick up switchers from all current therapies. In addition TYSABRI can be added to the current therapies for incremental benefit***….

> In summary . . . ***[t]he goal is for TYSABRI to be the number one MS product worldwide***, and we are very confident the MS franchise will continue to grow. [Emphasis added].

284. When asked during the Joint November 24, 2004 Conference Call to provide some clarity regarding the marketing strategy of Tysabri, Defendants engaged in the following exchange:

> Q: [M]y question relates to the fact that you did say that you were going to have sort of one sales force for promoting AVONEX as well as Antegren. Can you just comment what sort of the marketing message is going to be? Are you going to stress the results from the SENTINEL trial, can you please provide some clarity on that?
>
> A: ***Our goal is for TYSABRI to be the number 1 product in MS***, and we will be stressing the advantage of TYSABRI AS MONOTHERAPY. However, as I indicated there is portion of population that's quite satisfied with the AVONEX treatment today and we don't want to lose sight of servicing them and we want to stress the fact that for certain patients that are not well controlled today adding TYSABRI is a very viable option for physicians. [Emphasis added].

285. When asked about disclosure relating to immunosuppression on the Tysabri label as it related to use of Tysabri in combination with Avonex®, Defendants downplayed the dangers of the immunosuppressive effect as relating only to a lack of data, which Defendants did have as a result of numerous warnings discussed above, including reports of opportunistic infections associated with Tysabri therapy. Yet, Defendants engaged in the following exchange:

> Q: [T]he section of the package insert referring to immunosuppression and any comment that patients . . . who do not receive concurrent therapy because of the possibility of increased risk of infection. Can you elaborate on that?
>
> A: That really reflects the lack of data at the moment on that . . . . So, you know, I think this is an appropriate warning at the moment in light of the data that are available, but ***I think over the next few years that the language there will hopefully change as we better understand the value of adding those 2 products and TYSABRI and other immunodulators.***

286. Another similar exchange went as follows:

> Q: I took interest in the label and drug interactions that when you use the drug together, I guess, AVONEX reduces TYSABRI clearance by about 30% and it seems to do so without any real safety ramifications. I guess in my mind that raises all kinds of intriguing dose-related questions and the one I'll ask is, with the higher dose interferon products might you see even a larger reduction in clearance and might that actually be a positive?
>
> A: Interesting question. This is an observation and barely outside of the conventional limits of the bioequivalent being that, you can say 2 products are bioequivalent if their pharmacokinetic profile is plus or minus about 20% to 25%. So the 30% number with an arrow curve around it is barely outside of the conventional bioequivalent limits, and therefore, I am not sure exactly how to even interpret those data . . . . And we'll be doing some additional work indirectly around some of the issues you suggest because we are certainly going to try to help physicians and patients understand how to add this product on to any of the existing therapies or how to transition from one existing therapy to TYSABRI.

287. Upon conclusion of the Joint November 24, 2004 Conference Call, Kelly Martin again reemphasized that "the unmet medical need is significant and Tysabri will help meet that significantly and grow the marketplace both in the US, in Europe, and potentially other parts of the world very significantly over the near term."

288. Analysts, again, were fooled by Defendants' materially false and misleading statements, and reacted positively to the FDA approval, as follows:

- **Baird U.S. Equity Research -** "Tysabri Will Likely Be Huge**…**Based on compelling 1-year Phase III data with respect to relapse rates, we expect Tysabri to show substantial uptake in the MS market as a novel therapeutic agent."
- **CIBC World Markets** - "We believe Tysabri will be a blockbuster new treatment for MS and Crohn's Disease. We forecast peak sales potential for Tysabri of approximately $3 billion, based on what we believe to be conservative market penetration assumptions in these indications."
- **Piper Jaffray** - increasing estimates of Tysabri sales stating "we currently estimate $280M in Tysabri sales in 2005."

289. The statements identified above in the November 23, 2004 Press Release and the Joint November 24, 2004 Conference Call were materially false and misleading for the reasons set forth in paragraph 172 above.

290. After Defendants announced FDA approval of Tysabri, analysts further increased their guidance. For example, on November 28, 2004, Bear Stearns issued a report stating: "We also expect Biogen to reiterate that it expects Tysabri to become the number one MS drug in a class that it expects will top $6 billion in WW sales within 5 years."

291. On November 30, 2004, just two days later, Prudential Equity Group issued a report boosting Biogen's target stock price to $78 per share and declaring Tysabri the "***gold standard in the treatment of MS***." [Emphasis added]. That same day, CIBC World Markets increased its target stock price to $71 per share and increased its Tysabri revenue target to greater than $3 billion in peak sales. Similarly, Citigroup also raised its Tysabri sales estimates to $190 million for 2005 and $526 million for 2006.

292. On December 21, 2004, Defendants issued a press release containing identical disclosures to those contained in the earlier press releases with respect to the Tysabri clinical trials (the "December 21, 2004 Press Release"). With respect to the adverse events that purportedly occurred during the clinical trials, Defendants disclosed in the December 21, 2004 Press Release that:

> Common adverse events associated with TYSABRI include headache, fatigue, urinary tract infection, depression, lower respiratory tract infection, joint pain and abdominal discomfort. The rate of infection in both studies was approximately one per patient-year in both TYSABRI-treated patients and placebo-treated patients. Serious infections occurred in 1.3 percent of placebo-treated patients and 2.1 percent of TYSABRI-treated patients. Serious infections included bacterial infections such as pneumonia and urinary tract infection, which responded appropriately to antibiotics. TYSABRI has been associated with hypersensitivity

> reactions, including serious systemic reactions, which occurred at an incidence of less than 1 percent of patients.

293. The statements identified above in the December 21, 2004 Press Release was materially false and misleading for the reasons set forth in paragraph 172 above.

294. Defendants misled physicians as well about the true risks of Tysabri. For example, in a January 10, 2005 report, Piper Jaffray increased its earnings estimates for 2005 and 2006 to $1.75 and $2.19, respectively, and increased estimated revenues from Tysabri to $330 million in 2005, $1 billion in 2006, based upon "recent channel checks and discussions with physicians indicat[ing] a very high level of awareness and demand for Tysabri."

295. On January 11, 2005, Defendant Mullen presented at a healthcare conference with JP Morgan (the "January 11, 2005 Healthcare Conference"). During his presentation, Defendant Mullen touted the success of Tysabri, characterizing it as one of the "big achievements in 2004" and described Tysabri's potential to be a blockbuster drug, as follows:

> the big news for the last [ph] 12 months since maybe February is really TYSABRI, what we did with the one year data, the agreement we got with the FDA and the EMEA to file based on that one year data . . . . Currently Biogen Idec has 2 of the top 10 biologics worldwide . . . and ***we believe and we're very excited along with our partner Elan that TYSABRI will become third product to achieve this blockbuster status***. [Emphasis added]

296. Moreover, during the January 11, 2005 Healthcare Conference, Defendant Mullen praised Biogen's success as a leader in the MS market:

> We are the clear MS leader at this point and with the approval of TYSABRI that only strengthens [ph] that position. ***We think we are launching a second blockbuster in the same franchise area,*** and we've got a strong plan how those are going to code this together. TYSABRI represents the only major advance in the treatment of MS in nearly a decade. The launch activity has been executed just as we planned. We had a great deal of activity that's taken place over the last few weeks since we launched just after Thanksgiving to really communicate with the position and the payor community.

* * *

> ***For newly diagnosed patients, we see TYSABRI moving in first line position*** for the pool of patients that have quit the older therapies, we see TYSABRI establishing itself, the first new therapy in nearly a decade. [Emphasis added]

297. With respect to the market for Tysabri used in combination with Avonex®, Defendant Mullen then assured investors that Avonex® was the "ideal combination product along with Tysabri, it's the only product that has proven efficacy along side in addition to Tysabri."

298. During the January 11, 2005 Healthcare Conference, Defendant Mullen made further false assurances to analysts that Tysabri had a "favorable tolerability profile," a "[r]elatively low frequency [of] serious adverse events," and that "TYSABRI demonstrated a low rate of immuno-genicity [ph] with only 6% [indiscernible] developing persistent anti-bodies."

299. During the January 11, 2005 Healthcare Conference, Defendant Mullen also discussed Biogen's goals for the year, stating: "Goal number one for the year is pretty simple. We wanted to see TYSABRI as the number one MS product worldwide and put it on the half way. So as we leave the year we should be well on the trajectory to that goal." Moreover, from a financial perspective, Defendant Mullen praised Biogen's business and future prospects as follows:

> Turning to the financial side of this, Biogen Idec's superior economic returns have allowed us to reinvest more in innovation. Our net margin in reinvestment R&D is top 2 among biotech companies in CR&D [ph] reinvestment rate as percentage [indiscernible] about 30% and we think that's a sustainable model for quite sometime. And at the same time we can operate the whole business under the high net margin.
>
> [W]e had set for us some goal of 15% compounded annual growth rate from '04 through '07 on the top-line and 20% on the bottom -

> line. ***We certainly feel we're well on track on that in 2004, certainly with addition of TYSABRI, we feel we're well on track. I think 2005 certainly promises to be another pretty dynamic exciting year for us when we've got to get the goals done on TYSABRI*** . . . . [Emphasis added]

300. The statements made at the January 11, 2005 Healthcare Conference were materially false and misleading for the reasons set forth in paragraph 172 above.

301. On February 7, 2005, Biogen released its fourth quarter earnings from 2004 (the "February 7, 2005 Earnings Release"). In the February 7, 2005 Earnings Release, Defendant Mullen praised the Company's performance during 2004, highlighting FDA approval of Tysabri as one of Biogen's main accomplishments as follows:

> Biogen Idec had a momentous year in 2004, highlighted by the approval of TYSABRI based on one-year data. Our major R&D programs experienced their most productive year and strong performance in AVONEX and RITUXAN fueled revenue growth of 19% to $2.2 billion. This puts us on track to meet our long-term goals of achieving approximately 15% top and 20% bottom line operating performance.

302. In the February 7, 2005 Earnings Release, Defendants also reaffirmed their guidance as follows:

> **Financial Guidance**
>
> Biogen Idec today reaffirmed its long-term goal of achieving 15% compound annual revenue growth, and approximately 20% compound annual earnings per share (adjusted pro forma non-GAAP) growth through 2007.
>
> Given the launch investments behind TYSABRI, the Company is anticipating low double-digit growth for revenue and adjusted non-GAAP earnings in 2005. On this non-GAAP basis, the Company expects operating expenses to grow 12-14% over 2004 levels and its effective tax rate for 2005 to be in the range of 31-33%. As a result, the Company estimates that its 2005 non-GAAP earnings per share will be in the range of $1.60 to the low $1.70's.

303. On February 7, 2005, Defendants also held a conference call with analysts in which all of the Individual Defendants participated (the "February 7, 2005 Conference Call"). Defendant Mullen again reiterated earlier guidance with regard to the Company's plan for "15% top line and 20% bottom line growth through 2007" and attributed the Company's ability to reach that goal, in substantial part, to Tysabri as follows:

> The launch of TYSABRI a year and a half earlier than originally planned further supports our confidence in achieving this goal. In 2005 given the launch investment we have behind TYSABRI, the earnings and revenue growth should be roughly in line with each other, and we're looking at low double-digit growth.

304. Moreover, according to Defendant Kellogg, "[w]e believe that you should see the Biogen Idec performance outlook in 2005 as I mentioned earlier as highly dependent on the TYSABRI results." He provided earnings per share guidance for 2005 of between $1.60 to $1.70 per share. Moreover, "[w]e feel great about the broader direction of Biogen Idec and the financial strength of our company."

305. During the call, Defendants described Tysabri as a "blockbuster" product, a "major product" that Defendants thought "is going to be pretty big, obviously." With respect to Biogen's mission, Defendant Rastetter was quoted as saying that "TYSABRI of course represents fulfillment of Biogen Idec's mission to create new standards of care for serious diseases of high unmet medical need, and we continue in the same vein to invest at a high rate for our sector or for the pharma sector in research and development."

306. During the February 7, 2005 Conference Call, Robert Hamm, Senior Vice President, Immunology Business Unit at Biogen reiterated the Company's guidance on the anticipated market of Tysabri as follows:

> As background there are approximately 350,000 patients with the relapsing form of MS in the US today, about a 190,000 patients on therapy, which represent a penetration of approximately 55%.

> After a decade of available treatment, many patients remain untreated, and that's due to the high unmet need, which means that current therapies are partially effect, require frequent injections, and many patients are intolerant of the side-effect profile. ***TYSABRI meets these needs with a new way to fight MS with great efficacy data, dosing every 4 weeks, and with a good tolerability and safety profile.*** (Emphasis added).
>
> We expect the MS market to grow from 4 billion today to over 6 billion, driven by market expansion. This growth comes from bringing back the quitters of therapy. We estimate that over 50,000 patients in the US have left therapy and another 50,000 worldwide. TYSABRI will bring back many patients that have had no other options to date.
>
> Our market research indicates that TYSABRI is expanding the market. Newly diagnosed patients and quitters comprise the lion's share of monotherapy TYSABRI starts. The majority of switches to TYSABRI monotherapy are from breakthrough patients defined as 2 or more relapses in the past 2 years.
>
> * * *
>
> We are convinced of TYSABRI'S blockbuster potential.

307. With respect to Tysabri used in combination with Avonex®, Defendant Adelman assured analysts that "[r]esults from the SENTINEL trial, as reported in the TYSABRI package insert, demonstrate that TYSABRI added to Avonex® is safe and effective in the treatment of patients with relapsing MS."

308. Upon the news, analysts remained positive. According to a February 7, 2005 report issued by JP Morgan, analysts remained optimistic about Tysabri based upon the Company's implication that "Tysabri could reach booked revenues of $1.42 billion in 2007, which is in line with our $1.43 billion booked estimate derived from $1.93 billion in end user sales in 2007." That same day, as a result of Defendants' materially false and misleading statements, Bear Stearns raised its rating to "outperform."

309. The statements identified above in the February 7, 2005 Earnings Release were materially false and misleading for the reasons set forth in paragraph 172 above

310. Following Defendants' positive statements, analysts rode the Tysabri bandwagon and continued to raise targets. For example, in February 8, 2005, Cathay Financial and Jefferies raised their target stock price to $65 per share. Similarly, SG Cowen predicted that "Tysabri will become a multi-billion dollar therapy in MS" and raised 2005 worldwide sales estimate from $200 million to $250 million. That same day, CIBC World Markets praised Tysabri's success, asserting that:

> We believe Tysabri's efficacy and safety profile will continue to drive its widespread adoption in first-and second-line MS therapy. On its 4Q04 conference call, Biogen Idec estimated that by 2007, revenues from Tysabri would be as large as Avonex revenues, which are $1.4 billion. This agrees with our estimates that Tysabri will be a blockbuster treatment for MS and Crohn's disease. We forecast peak sales potential for Tysabri of approximately $4 billion in 2010-2011, based on what we believe to be reasonable market penetration assumptions in these indications.

311. On February 17, 2005, ***long after*** patients had already begun to exhibit PML symptoms, Defendants issued a press release (the "February 17, 2005 Press Release") touting the efficacy of Tysabri, under the headline "Tysabri® Two-Year Monotherapy Trial Demonstrates Significant Impact on Disability Progression and Relapse Rate in Multiple Sclerosis: Data Show 42% Reduction in the Risk of Disability Progression and Sustained 67% Reduction in Relapse Rate."

312. The February 17, 2005 Press Release also contained the following materially misleading statements with respect to results of phase III in the MS trials:

> Biogen Idec (NASDAW: BIIB) and Elan Corporation, plc (NYSE: ELN) announced today that the Phase III TYSABRI® (natalizumab) AFFIRM monotherapy trial achieved the two-year primary endpoint of slowing the progression of disability in patients with relapsing forms of multiple sclerosis (MS).

> TYSABRI treatment led to a 42 percent reduction in the risk of disability progression relative to placebo. These data also demonstrated a 67 percent reduction in the rate of clinical relapses over two years, which was sustained and consistent with the previously reported one-year results.

313. Defendant Adelman praised the Tysabri and the success of the Phase III trials as follows:

> TYSABRI, with its significant effect on slowing the progression of disability, offers new hope for patients with MS. With these data, we gain a more complete understanding of the broad therapeutic benefit of TYSABRI in MS.

314. Lars Ekman, MD, Elan's Executive Vice President and President of Research and Development at Elan, echoed Defendant Adelman's comments, remarking that "[r]esults from the two-year monotherapy clinical trial mark a major milestone in the treatment of MS. ***These two-year data strengthen our belief that TYSABRI will become the leading therapy for MS patients***."

315. With respect to adverse events that purportedly occurred in the Phase III trials, Defendants reported that:

> The adverse event profile at two years was also consistent with previously reported results. Common events included headache, fatigue, urinary tract infection, depression, lower respiratory tract infection, limb and joint pain, and pharyngitis. The incidence of infections in TYSABRI-treated and placebo-treated patients was similar. Serious infections occurred in 3.2 percent and 2.6 percent of patients, respectively. These included bacterial infections such as pneumonia and urinary tract infection, which responded appropriately to antibiotics. TYSABRI has also been associated with hypersensitivity reactions, including serious systemic reactions that occurred at an incidence of less than 1 percent of patients.

316. The statements identified above in the February 17, 2005 Press Release were materially false and misleading for the reasons set forth in paragraph 172 above. Moreover, the statements made in the February 17, 2005 Press Release were materially false and misleading

because Defendants knew that, in addition to the other opportunistic infections that occurred previously, as discussed above, two patients had developed signs and symptoms of PML and thus, Tysabri would never "become the leading therapy for MS patients" and rather would only be a last resort therapy.

317. In response to Defendants' materially false and misleading statements about the success of the two-year Phase III data concerning Tysabri as a treatment for MS, analysts remained excited as follows:

- **Deutsche Bank** 2/17/05 report – "Stellar Tysabri data continue to support MS blockbuster."
- **Citigroup** 2/17/05 report -Tysabri clinical trial results "reinforce the superior efficacy and safety profile of Tysabri and support the premise that Tysabri has the potential to become the leading therapy for MS."
- **Morgan Stanley** 2/17/05 report - "we believe Tysabri has become the standard of care in the treatment of multiple sclerosis, we expect this data to be added to the label by the FDA, and we believe that ultimate market share for this drug may approach 50%."
- **JPMorgan** 2/17/05 report - "We believe that longer term efficacy, disability and safety data solidify the clinical side of the Tysabri story, and that this data puts further distance between Tysabri and the competition."
- **SG Cowen** 2/17/05 report - "Positive 2-Year Data Position Tysabri To Own The MS Market."
- **CSFB** 2/17/05 report - "We believe this two-year data will support the rapid evolution of Tysabri as the first-line standard of care agent in relapsing-remitting MS . . . Stock upside could reach $80 or more . . ."

Two Tysabri Patients Are Diagnosed With PML

318. Defendants claim that on February 18, 2005 they became aware that one patient in the MS SENTINEL trial (combination therapy of Tysabri with Avonex) had been diagnosed with PML and that there was another suspected case of PML in a patient participating in the same clinical trial. An internal memorandum from Biogen and Elan to physicians participating in the

Tysabri clinical trial dated February 28, 2005, however, sets forth a markedly different timeline. According to the internal memorandum, the two patients in the MS clinical trials who developed PML, a "46-year-old female" and a "46-year-old male," showed neurological problems as early as November 2004.

319. The internal memo further explained that the 46-year-old female was hospitalized on February 12, 2005 where she underwent an MRI that "suggested a differential diagnosis that included PML." A review of this patient's autopsy report revealed that the patient actually began experiencing PML symptoms in November 2004, right around the time Defendants were expecting to receive FDA approval of Tysabri. The autopsy report further reported that, consistent with the internal memorandum, the patient's PML symptoms had worsened by December 2004 and that the patients MRI showed lesions that were atypical of MS and were, in fact, typical of PML.

320. With respect to the second patient, a 46-year-old male, the internal memorandum disclosed that, in December 2004, the patient "developed slow thinking, slurred speech and cognitive dysfunction . . .," which, as discussed above, are symptoms consistent with symptoms associated with PML, such as impaired cognition and difficulty thinking. Moreover, according to a *New England Journal of Medicine* article dated June 9, 2005, this patient began exhibiting symptoms of PML in October 2004 when the patient was found to have atypical frontal lesions. The article further reported that, by November 2004, this patient's physician noted "uncharacteristic, inappropriate behavior during a routine study visit" and, by December 2004, "new MRI lesions were seen consistent with PML," at which point dosing of Tysabri was terminated by the treating physicians in an attempt to restore the patient's immune system.

321. As Defendant Adelman soon after admitted at an SG Cowen Annual Healthcare Conference held on March 16, 2005, with respect to the first PML case, "it is very clear that from the signs and the symptoms the ***PML related symptoms started much much earlier than when the diagnosis was made***." With respect to the second PML case, Defendant Adelman further conceded that while "[t]he other case . . .got this diagnos[is] much faster, [] ***and the prudent action was not taken***." [Emphasis added]

322. Defendants similarly acknowledged at the March 2006 FDA Hearing that, consistent with the February 28, 2005 internal memorandum and biopsies, the two PML patients in the MS trial began experiencing PML symptoms in October and November 2004 (FDA Tr., 150), right about the time Defendants were expecting to receive FDA approval of Tysabri. Yet Defendants concealed these serious adverse events from the public and from the FDA, until after Biogen and Elan received FDA approval for Tysabri.

323. Coincidentally, Biogen insiders dumped large blocks of stock after February 12, 2005, when the first PML patient was hospitalized, and in the days leading up to and on February 18, 2005. For example, on February 18, 2005, Thomas J. Bucknum, dumped 89,700 shares of stock, reaping approximately $6 million in proceeds for a profit of $1.9 million; on February 15, 2005, Defendant Rastetter sold 120,313 shares reaping proceeds of $8.15 million; and, on February 14, 2005, Craig Schneier sold 3,500 shares for proceeds of $233,100 and Robert Pangia, a Biogen Director, sold 15,750 shares reaping $1,055,250.

VII. THE TRUTH BEGINS TO EMERGE

324. At 7:59 a.m. on February 28, 2005, prior to the opening of trading, Biogen and Elan, issued a joint press release, announcing their "Voluntary Suspension of TYSABRI" and disclosing that they had "suspended dosing in all clinical trials" (the "February 28, 2005 Press Release"). The February 28, 2005 Press Release stated, in relevant part:

> This decision is based on very recent reports of two serious adverse events that have occurred in patients treated with TYSABRI in combination with AVONEX® (Interferon beta-1a) in clinical trials. These events involve one fatal, confirmed case and one suspected case of progressive multifocal leukoencephalopathy (PML), a rare and frequently fatal, demyelinating disease of the central nervous system. Both patients received more than two years of TYSABRI therapy in combination with AVONEX.
>
> The companies' actions have been taken in consultation with U.S. Food and Drug Administration (FDA). Worldwide regulatory agencies are being kept informed.
>
> The companies will work with clinical investigators to evaluate TYSABRI-treated patients and will consult with leading experts to better understand the possible risk of PML. The outcome of these evaluations will be used to determine possible re-initiation of dosing in clinical trials and future commercial availability.

325. Defendants' suspension of Tysabri required them to alert medical professionals and, accordingly, Defendants sent a "Dear Healthcare Professional" letter to physicians, signed by Defendants Adelman and Lars Ekman, Elan's Executive Vice President and President of Research and Development, advising physicians of the Company's decision to suspend the drug. *See* Tysabri website, available at: www.tysabri.com.

326. Later that morning, Defendants held a conference call with analysts to discuss the voluntary suspension of Tysabri, during which Defendants Mullen and Adelman and more than six hundred people from the media and investment community participated (the "February 28, 2005 Conference Call").

327. During the February 28, 2005 Conference Call, Defendant Mullen advised that, in light of the two reported cases of PML, "it is prudent to take a step back and evaluate the possible risk of PML." Accordingly, Defendant Mullen assured investors that Biogen and Elan would conduct an investigation of the two PML cases, "review the MRI scans of Tysabri-treated patients who were in our clinical trials," "evaluate Tysabri-treated patients who were in our

clinical trials," and "work with leading experts in PML to deepen our understanding of the disease and any possible links to Tysabri."

328. Defendants admitted in the February 28, 2005 Conference Call that there is a presumption that Tysabri is linked to causing PML. According to Defendant Mullen, "[a]ny time we see a safety signal, the assumption — the starting assumption is it's associated until we can demonstrate that it's not." Similarly, Defendant Adelman admitted that "if indeed the second case turns out to truly be PML, then one might say that isn't there a signal associated with combination and perhaps long-term therapy." When asked whether the two PML patients had any other common characteristics that might explain the PML, Defendant Adelman dismissed the possibility that there was any other cause of the PML other than Tysabri, stating that "outside of having multiple sclerosis and being in the trial, there's no shared characteristics."

329. When specifically asked during the February 28, 2005 Conference Call about Tysabri's immunosuppressive effect, Defendant Adelman flatly denied any knowledge of prior opportunistic infections occurring during the Tysabri clinical trials, despite the eventual admissions Defendants would later make at the March 2006 FDA Hearing (discussed above), which directly contradict Adelman's statements. The exchange between Craig Parker, an analyst for Lehman Brothers, and Defendant Adelman proceeded as follows:

> CRAIG PARKER, ANALYST, LEHMAN BROTHERS: Burt, it seems to me that the key issue is immunosuppression. So I'm wondering if you saw evidence of systemic or CNS immunosuppression in those two patients, and specifically T-cell counts; and whether you've seen any evidence at two years in either monotherapy or combination therapy patients from the trials.
>
> DR. BURT ADELMAN: Right. So in fact, we have no evidence in human or animal studies that short-term or long-term treatment with ***Tysabri*** is associated with declines in lymphocyte numbers or any real other signal of significant immune dysregulation. As a matter of fact, we thought of this product as predominantly impacting transit across microvasculature of immune cells bearing

> the receptor, rather than actually as a drug whose major mechanism of action was to alter immune cell activation or function.
>
> BILL TANNER, ANALYST, LEERINK SWANN: Maybe a question for you Burt, just curious to what is known about T-cell turnover in the CNS and curious as to whether or not the effect that you're seeing wouldn't be expected if you are blocking migration of T-cells in and then you've got some turnover of resident T-cells in the CNS.
>
> DR. BURT ADELMAN: Right. So we're going to learn more about that. What I think I understand at the moment is that the brain does not have lymphatics. So the only way for immune cells to gain access to the brain is through the microvasculature. That's all I really know.

330. Upon the news, the stock market reaction was swift and severe, erasing approximately $9.6 billion dollars in shareholder value, leaving Biogen with market capitalization of only $13 billion. Biogen shares plunged 42.5 %, falling $28.63 to close at $38.65 on trading volume of 118 million shares, more than thirty times the average daily trading volume during the Class Period. Notably, this was nearly four times the highest trading volume in Biogen's history. Comparatively, on that same day, the S&P 500 Index decreased only 2.6 % and the S&P Biotechnology Index increased 1.7 %. Biogen's stock price hovered in the mid-thirties and only began a gradual increase beginning in the Fall 2005, after the Company announced its plans to submit its supplemental Biologics License Application to the FDA to return Tysabri to the U.S. market.

331. Similarly, Elan lost approximately $7.5 billion, or 70 % of its market value. Elan's American Depository Shares[9] plummeted $18.90 per share to close at $8.00 per share and

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[9] Elan's common stock trades on the NYSE in the form of American Depository Shares. Each ADS is equivalent to one share of common stock. Elan's common stock also trades on the Dublin and London Exchanges.

fell 13.81 euros, or 68%, to close at 6.49 euros on the Dublin exchange, on unusually high volume of 167 million shares, nearly twenty-nine times the average trading volume during the Class Period and the highest trading volume ever in Elan's history. Like Biogen, Elan ADSs did not recover after the February 28, 2005 Press Release, trading consistently below $10 per share, until late 2005.

332. Neither Biogen's nor Elan's stock has returned to its previous Class Period high.

333. Following the Company's announcement, on February 28, 2005, analysts cut their ratings of Biogen common stock. For example, Bear Stearns cut its rating to "underperform." Similarly, Deutsche Bank cut its rating to "sell," and CSFB to "neutral," based upon concerns that "Tysabri, if it were to re-launch, would have substantially diminished prospects." Jefferies reduced its rating to "hold" and CIBC World Markets to "sector perform." Moreover, Citigroup decreased its target stock price to $49 per share from $70 per share and Morgan Stanley cut its target price to $57 per share from $77 per share citing concerns that "[w]ithdrawal of Tysabri threatens long-term growth."

334. On March 1, 2005, a *New York Times* article cited Dr. Lawrence Steinman a leading MS expert and co-inventor of Tysabri, as calling the PML deaths an "***unfortunately logical***" result given that Tysabri works by suppressing the immune system. According to Dr. Steinman, as he previously warned on numerous occasions, Tysabri should not have been approved based upon only one year's data. Dr. Steinman was quoted in the article as stating: ***"I'm shocked that it happened so soon, but I knew it was going to happen sooner or later***." *The New York Times* article reported that, according to Dr. Steinman, he had expressed his apprehensions about Tysabri in speeches and in a July 2004 article in the journal *Science* and ***was asked by Biogen executives to "tone down criticisms of the drug."***

335. A March 1, 2005 *Wall Street Journal* article described PML as a "devastating" disease and reported that, contrary to analysts' expectations of Tysabri "quickly becom[ing] a blockbuster with annual sales of over $2 billion within a couple of years," there is "a lower market potential" than Defendants had represented.

336. On March 2, 2005, the *Los Angeles Times* published an article stating, in relevant part, as follows:

> ***Researchers familiar with Tysabri said they weren't surprised to learn that patients had become infected with the deadly virus.*** Emmanuelle Waubant, a neurologist at UC San Francisco, said PML didn't show up in the one-year data because such infections take long to develop.
>
> In patients with HIV, it takes several years of having their immune system compromised to develop this virus, she said. It is not surprising it took two years in each [Tysabri] case, she said. "There is a reason why these studies were designed to take two years." [Emphasis added.]

337. In the following days, after digesting the news, analysts continued to downgrade Biogen's stock. On March 1, 2005, Lazard Freres downgraded Biogen to "hold" and Piper Jaffray downgraded the stock to "market perform" citing concerns of "the continued uncertainty surrounding the future of the Tysabri's franchise." Analysts also decreased estimated future revenues from Tysabri. For example, a March 4, 2005 *Boston Herald* article predicted that, "*if*" Tysabri returns to the market, "it will be a much meeker performer than the $4 billion blockbuster" Elan and Biogen had hoped for. Eric Schmidt, an analyst for SG Cowen Securities Corp., estimated revenues would be between $300 million and $500 million. Merrill Lynch reduced its estimate to $1.4 billion from $3.1 billion, assuming Tysabri would only be used in patients who do not improve on other treatments. Similarly, Goodbody Stockbrokers said Tysabri sales could be as low as $350 million in 2009 versus its original forecast of $2 billion. Morgan Stanley cut sales estimates to $1.2 billion from $1.7 billion.

VIII. POST CLASS-PERIOD EVENTS

A. The Aftermath Of The Withdrawal Of Tysabri From The Market

338. On March 4, 2005, an article issued on *Bloomberg L.P.* reported that the second suspected PML case had been confirmed. Upon the announcement, Biogen's shares closed at $37.53 per share, down $1.80 per share, or 4.6 % from the previous day's closing price of $39.33, on trading volume of approximately 24 million shares, more than six times the normal average daily trading volume during the Class Period.

339. On March 9, 2005, Biogen announced that Thomas Bucknum, Executive Vice President and General Counsel, had "resigned from the company." In particular, Defendant Thomas Bucknum, Executive Vice President and General Counsel of Biogen, ***was able to sell 89,700 shares of Biogen stock, reaping approximately $1.9 million*** in proceeds from such sale on February 18, 2005. Defendant Bucknum executed this sale after learning at approximately 12:00 p.m. that day at a meeting with other Biogen senior officers that a patient participating in the Tysabri clinical trials had been diagnosed with PML. In addition, Defendant Bucknum received approval from the Company's legal department for this sale.

340. As a result of Defendant Bucknum's insider selling, the SEC filed a settlement enforcement action complaint (the "SEC Complaint") against him based upon his violations of the Securities Act of 1933 and the Exchange Act, as well as his breach of fiduciary duty to the Company and its investors. Accordingly, the SEC announced that it had ***entered into a settlement agreement with Bucknum to pay $3 million in disgorgement, interest and penalties and prohibiting Bucknum from serving as an officer or director of a public company for five years***. On March 9, 2005, Biogen announced that Defendant Bucknum had "resigned from the company" as a result of insider trading allegations.

341. The *Los Angeles Times* published an article providing specifics with respect to the infection rate and adding that FDA officials lacked sufficient information about Tysabri's long-term effects. The article stated, in relevant part, as follows:

> In hundreds of pages of documents that offered the first detailed look at the FDA's handling of the drug, reviewers noted that Tysabri appeared more effective than existing drugs, reducing relapses in patients by 66%, based on one year's data. The reviewers said it was "reasonably likely" that the drug would provide long-term benefits.
>
> Nonetheless, the agency's drug reviewers acknowledged they were unsure about Tysabri's long-term effects.
>
> The clinical meaningfulness of a decrease in the incidence of relapses at one year is uncertain.
>
> FDA reviewers found that Tysabri had an acceptable safety profile, though they noted that health risks 'beyond one year are not known.'
>
> Infections, including urinary and respiratory, were seen with Tysabri, but they were 'generally routine and did not have a complicated course.'
>
> Stanford University professor Dr. Lawrence Steinman, an MS specialist, had warned there was a clear risk of infection for patients taking such drugs, because they tend to suppress the body's immune system.
>
> Steinman had helped discover the active agents in the drug, but later became concerned about potential side effects, and is working on a competing drug. ***He noted that the infection rate of Tysabri patients in one trial was 2.1%, compared with 1.3% in the placebo group***.
>
> '***There were hints of an increase in the infection rate,' said Steinman. 'The FDA should have dug deeper***.' [Emphasis added].

342. On March 31, 2005, before the market opened, *The Boston Globe* reported that a ***third patient had died from PML back in December 2003***. As reported by *The Boston Globe*, the third case of PML resulted from a patient taking Tysabri in the Crohn's trial, who was

previously misdiagnosed in June 2003 with malignant astrocytoma, a kind of brain cancer. The patient reportedly had taken eight doses of Tysabri over an 18-month period. Unlike the two patients previously diagnosed with PML who were taking Tysabri in combination with Avonex®, the Crohn's patient had previously taken other immunosuppressive drugs but had ceased doing so eight months prior to developing PML. Thus, this cast doubt on the belief that Tysabri, taken with Avonex®, caused the PML, and rather indicated that Tysabri itself was the real culprit.

343. A healthcare strategist at New York-based Miller Tabak & Co., Les Funtleyder, reportedly described the third confirmed case of PML as a "death blow" particularly given that the patient was taking Tysabri as a monotherapy, rather than in combination with Avonex®, as in the other two PML-related deaths. Specifically, Funtleyder described this latest development as a "death blow" to Biogen and Elan, as follows:

> Biogen Idec expected Tysabri to help win a greater share of the MS market as growth slows for its eight-year-old Avonex drug. Yesterday's setback leaves Biogen Idec with few options for building sales. At most Tysabri might be allowed on the market in a salvage role for those whom nothing else works and their disease is progressing. ***The fact that the case was a monotherapy is really bad, it's almost like a death blow***. [Emphasis added].

344. Upon this news, Biogen's stock closed at $34.51 per share, dropping $3.84 per share, or 10%, from the previous day's closing price of $38.35, on trading volume of 41 million shares.

345. On July 21, 2005, *The Boston Globe* reported that the family of one of the PML victims who died in February 2005 filed a wrongful death suit against Defendants alleging that Elan and Biogen knew of the potential dangers associated with taking Tysabri "yet recklessly proceeded with tests in clinical trials" (the "Wrongful Death Suit"). Moreover, the Wrongful

Death Suit alleges that Elan and Biogen did not disclose the dangers and risks of Tysabri to the patient.

346. A *Boston Globe* article, dated August 11, 2005, provided an update on the screening of patients who took Tysabri in the MS trials and noted no new cases of PML. Analysts and physicians reportedly remained skeptical. Dr. Aaron Miller, Chief Medical Officer of the National Multiple Sclerosis Society and Medical Director at Corinne Goldsmith Dickinson Center for Multiple Sclerosis in New York told the *Globe* that he thought it would be reasonable to use Tysabri only "***in patients who are seriously ill and are not responding to other therapies***." Similarly, analysts believe that "***because of the higher risks associated with the drug, Tysabri may be reserved for much smaller subsets of MS patients***" and that Tysabri "***would most likely be used for patients who haven't responded to existing therapies and those for whom the treatments no longer provide significant benefits.***" [Emphasis added]

347. On September 26, 2005, Elan and Biogen reported that they had submitted their supplemental biologics license application ("sBLA") to the FDA for Priority Review. The sBLA contained a substantially more detailed and a stricter warning label and limited distribution than that previously submitted in 2004. Biogen disclosed its risk management plan as follows:

- completion of final two-year data from the Phase III AFFIRM monotherapy trial and SENTINEL add-on trial with AVONEX® (Interferon beta-1a) in MS;
- ***integrated safety assessment*** of patients treated with Tysabri in clinical trials; and
- revised label and risk management plan

348. According to the Biogen and Elan, the companies planned to submit a similar data package to the European Medicines Agency. Defendant Adelman disclosed, at a Reuters

Biotechnology Summit, that "[w]e are looking at usage as a monotherapy, we are not going to advocate combination therapy."

349. Moreover, in a *Reuters-Summit* news article, Defendant Adelman stated that Elan and Biogen were developing a package insert label for Tysabri that would adequately explain potential risks of the drug, especially for patients that might already be "immune-compromised." Defendant Adelman further informed that Biogen was advocating creating a "registry of patients taking Tysabri" to track the safety of the medication and identify others who were in danger of developing PML. According to Defendant Adelman, the patient registry was intended to "slow the process down and …make people think twice" about taking Tysabri. He predicted the demand for Tysabri would be "much more modest" if and when Tysabri became available.

350. On November 17, 2005, the FDA accepted Elan and Biogen's sBLA.

351. On February 15, 2006, in late afternoon, shortly before the market closed, Elan and Biogen announced that the FDA had removed the hold on the Tysabri clinical trials in the U.S. The companies reported that they "expect to begin an open label, multi-center safety extension study of TYSABRI monotherapy in the U.S. and internationally in the coming weeks. Patients who previously participated in the Phase III MS program are eligible for entry."

352. The next day after the market had time to digest the news, Biogen's stock rose, closing at $47.33 per share, up $1.61 per share, or 3.5%, from the previous day's closing price of $45.72, on trading volume of 64.9 million shares.

353. On February 28, 2006, Piper Jaffray reported on a survey they conducted involving 140 neurologists (27% of whom prescribed Tysabri), which revealed that only 59% of neurologists thought Tysabri should return to the market. According to the doctors surveyed, they only expected to prescribe Tysabri to 10% of their patients. Approximately 57% of those

doctors believed Tysabri's effectiveness was only worth the risk of opportunistic infections, such as PML, with patients who have not responded to other MS drugs and only 6% would use Tysabri as a first-line therapy on newly diagnosed patients.

354. The same day, the American Academy of Neurology announced the results of a study showing that Tysabri could damage the immune system as much as HIV infection.

355. Upon the news, Biogen's stock dropped, closing at $47.25 per share, down $2.85 per share, or 6.03%, from the previous day's closing price of $50.10, on trading volume of 10.1 million shares.

356. On March 7-8, 2006, the FDA Advisory Committee met to hear Biogen and Elan's revised safety plan and vote on whether Tysabri should be returned to the market in any capacity. The FDA Advisory Panel unanimously recommended reintroduction of Tysabri for treatment in relapsing forms of MS in a 12-0 vote on March 8, 2006. The Panel, however, voted 7-5 to leave to the physicians, the decision for which MS patients to prescribe Tysabri.

357. Investors were delighted with the FDA Advisory Panel's recommendation to return Tysabri to the market with essentially no restrictions on its use. Trading was suspended during the two-day FDA hearing. On March 9, 2006, the day following the FDA's announcement, Biogen's stock rose, closing at $47.54 per share, up $2.03 per share, or 4.5% from the previous day's closing price of $45.51, on trading volume of 14.5 million shares.

358. On April 28, 2006, Elan announced that a drug advisory panel to the European Union recommended that Tysabri should be approved only for patients with the most severe disease or those who have not been helped by other treatments.

B. **The FDA Allows Tysabri To Re-Enter The Market With Restricted Distribution**

359. On June 5, 2006, the FDA announced it "approved an application for resumed marketing of Tysabri (natalizumab) ***subject to a special restricted distribution program***." [Emphasis added]. The FDA approval restricted use of Tysabri only as a monotherapy and not in combination with other drugs. Moreover, the FDA recommended use of Tysabri essentially as a salvage therapy for "patients who have not responded adequately to, or cannot tolerate, other treatments for MS." The final FDA approval was far more restrictive than the recommendations of the FDA Advisory Panel that reviewed Biogen and Elan's request to return Tysabri to the market on March 7-8, 2006.

360. As a condition of allowing Tysabri back on the market, the FDA required the drug to carry the FDA's strictest black box warning label and that it be available only under a restricted distribution program. The drug would also be subject to a comprehensive safety and risk management plan and the strictest measures to monitor the side effects of Tysabri.

361. The main features of the risk management plan, called the TOUCH (Tysabri Outreach Unified Committee to Health) Prescribing Plan, consisted of the following:

- Revised labeling with prominent black box warning of the risk of PML and warning against concurrent use with chronic immunosuppressive or immunomodulatory therapies or in patients who are immunocompromised;
- Tysabri will only be prescribed, distributed, and infused by prescribers, infusion centers, and pharmacies registered with the program;
- Tysabri will only be administered to patients who are enrolled in the program;
- Prior to initiating the therapy, health care professionals are to obtain the patient's Magnetic Resonance Imaging (MRI) scan to help differentiate potential future multiple sclerosis symptoms from PML;
- Mandatory FDA review of educational tools for patients and physicians, including a patient medication guide, TOUCH enrollment form, and a monthly pre-infusion checklist;

- Patients on Tysabri are to be evaluated at 3 and 6 months after the first infusion and every 6 months after that, and their status will be reported regularly to Biogen and Elan; and
- A 5,000 patient cohort observational study, which will be performed over five years, called the Tysabri Global Observation Program in Safety study.

362. The new Tysabri label, obtained from the FDA website, contains the following prominent Black Box warning:

> WARNING
>
> TYSABRI® increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability.
>
> Although the cases of PML were limited to patients with recent or concomitant exposure to immunomodulators or immunosuppressants, there were too few cases to rule out the possibility that PML may occur with TYSABRI® monotherapy.
>
> Because of the risk of PML, TYSABRI® is only available through a special restricted distribution program called the TOUCH™ Prescribing Program. Under the TOUCH™ Prescribing Program, only prescribers, infusion centers, and pharmacies associated with infusion centers registered with the program are able to prescribe, distribute, or infuse the product. In addition, TYSABRI® must be administered only to patients who are enrolled and meet all conditions of the TOUCH™ Prescribing Program (**see WARNINGS, Progressive Multifocal Leukoencephalopathy, and Administration Program for TYSABRI®).**
>
> Healthcare professionals should monitor patients on TYSABRI® for any new sign or symptom that may be suggestive of PML. TYSABRI® dosing should be withheld immediately at the first sign or symptom suggestive of PML. For diagnosis, an evaluation that includes a gadolinium-enhanced magnetic resonance imagine (MRI) scan of the brain and, when indicated, cerebrospinal fluid analysis for JC viral DNA are recommended **(see CONTRAINDICATIONS and WARNINGS, Progressive Multifocal Leukoencephalopathy)**

363. Tellingly, the WARNINGS and ADVERSE REACTIONS sections of the label now contain warnings about specific severe opportunistic infections, such as PML, herpes virus infections, cryptosporidial gastroenteritis, pneumocystis carinii pneumonia, pulmonary

mycobacterium avium intracellular, bronchopulmonary aspergillosis, and Burkholderia cepacia infection, which were not contained in the original label for Tysabri approved in November 2004. These opportunistic infections are the very same infections that occurred during the Tysabri clinical trials.

364. Moreover, the label included an extensive discussion of PML and the three confirmed cases of PML. Under the heading "Immunosuppression," the new label, unlike the original label, contains the following warning:

> **Immunosuppression**
>
> The immune system effects of TYSABRI® may increase the risk for infections. In Study 1, certain types of infections, including pneumonias and urinary tract infections (including serious cases), gastroenteritis, vaginal infections, tooth infections, tonsillitis, and herpes infections occurred more often in TYSABRI®-treated patients than in placebo-treated patients (**see WARNINGS, Progressive Multifocal Leukoencephalopathy (PML); and ADVERSE REACTIONS, General Infections**). One opportunistic infection, a cryptosporidial gastroenteritis with a prolonged course was observed in a patient who received TYSABRI® in Study 1.
>
> Concurrent use of antineoplastic, immunosuppressant, or immunomodulating agents may further increase the risk of infections, including PML and other opportunistic infections, over the risk observed with use of TYSABRI® alone **(see BOXED WARNING; WARNINGS, Progressive Multifocal Leukoencephalopathy (PML); and ADVERSE REACTIONS, Infections).** The safety and efficacy of the prior label did not disclose that TYSABRI® in combination with antineoplastic, immunosuppressant, or immunomodulating agents have not been established.
>
> Concurrent use of short courses, of corticosteroids was associated with increase in infections in Studies 1 and 2. However, the increase in infections in TYSABRI®-treated patients who received steroids was similar to the increase in placebo-treated patients who received steroids.

365. In July 2006, Tysabri was re-introduced to the market for commercial consumption.

366. According to a June 5, 2006 *Wall Street Journal* article, "[t]he prospects of using Tysabri with other MS treatments was a major reason the drug was originally thought to have huge sales potential. Analysts now have dimmer expectations." A June 6, 2006 article in *Global Insight* echoed *The Wall Street Journal* article, predicting that the severe restrictions imposed on Tysabri "look set to significantly dampen sales of Tysabri" particularly recognizing that the impact was "likely to prove a greater problem for Elan than Biogen. Elan is more dependent on Tysabri sales to improve its operating outlook . . . ."

367. Following the Company's announcement, analysts sharply cut their ratings of Biogen, reacting to the news confirming that the market for Tysabri was significantly less than anticipated. For example, Citigroup and Jefferies issued a "hold" recommendation and ranked Biogen stock a high risk. Similarly, Bear Stearns rated Biogen "underperform" and JP Morgan rated it "overweight."

368. Moreover, analysts also reduced their future Tysabri sales estimates, well below Defendants' initial prediction of $4+ billion. For example, Christopher Raymond of Robert W. Baird & Co. estimated Tysabri sales of several hundred million per year, much less than that originally estimated in the billions. Similarly, a Piper Jaffray analyst predicted "the drug may reach $1 billion in annual sales in a best-case scenario." Geoffrey C. Purges of Sanford C. Bernstein & Co. estimated sales of only $35 million in 2006, rising to $946 million by 2001, and RBC Capital Markets analyst Jason Kantor estimated U.S. sales of only $36 million in 2006, $439 million in 2007, and $806 million by 2008.

369. While presenting an overview of Tysabri at a meeting with fellow researchers on June 19, 2006, Defendant Adelman conceded that Biogen and Elan had not sufficiently focused on the safety of Tysabri, stating: "We have to make sure we fully understand the mechanism of action that we're dealing with, and what the potential upsides and downsides of that mechanism are." According to Defendant Adelman, more preclinical testing should be required. As discussed above, neurologists such as Dr. Miller had previously recommended that Biogen do just that and perform animal studies to fully determine Tysabri's safety profile. Yet, Defendants did not heed Dr. Miller's earlier warnings or advice.

370. On June 29, 2006, Biogen and Elan announced that "Tysabri was approved by European regulators ***for patients with the severest cases of [MS]***." [Emphasis added]. Similar to the FDA, the European Union also limited the use of Tysabri to patients "who haven't been helped by older treatments."

371. In light of the FDA's limitations on the use of Tysabri, analysts remain doubtful of its revenue potential. For example, a July 26, 2006 *DataMonitor* article, entitled "Elan/Biogen Idec: Tysabri Back on the Shelves; Elan and Biogen Idec's Multiple Sclerosis Drug Tysabri Has Returned to the Market," reported that forecasts for future Tysabri sales have "plummeted." Moreover, according to *DataMonitor*, "it appears that, despite its efficacy, the safety concerns shrouding Tysabri are likely to have bulldozed its market potential indefinitely." Similarly, a July 26, 2006 *MarketWatch* article reported that, according to Citigroup analysts Elise Wang, '"[w]e continue to expect a relatively slow ramp-up in sales for Tysabri . . . ."'

372. Since reapproval by the FDA in June 2006, Tysabri sales have been minimal. According to one analyst at Piper Jaffray, Deborah Knobelman, the feedback that she has received from physicians, thus far has shown that the prescription rates of Tysabri were slower

than she had anticipated in the U.S. because of safety concerns, reimbursement procedures, and patient-monitoring requirements. Accordingly, Knobelman slashed her estimate for worldwide Tysabri sales to just $21 million for 2006, down from her previous estimate of $123 million, a decrease of 83%.

373. As demonstrated herein, Tysabri is not, and was never going to be, the blockbuster drug that Defendants promised investors.

IX. CAUSATION ALLEGATIONS

374. Biogen's common stock was traded on the Nasdaq at all relevant times. As described above, Defendants' material misrepresentations and omissions had the effect of creating and maintaining an artificially inflated price for Biogen's common stock. Those misrepresentations and omissions that were not immediately followed by an upward movement in the Company's stock price served to maintain the share price at artificially inflated levels by maintaining and supporting the false public perception of Biogen's business, operations, performance and prospects, and particularly of Tysabri as a purported "blockbuster" drug.

375. Defendants had a duty to disseminate promptly accurate and truthful information with respect to Biogen's financial and operational condition or to cause and direct that such information be disseminated and to correct promptly any previously disseminated information that was misleading to the market. As a result of their failure to do so, the price of Biogen's common stock was artificially inflated during the Class Period, severely damaging Lead Plaintiffs and the Class.

376. Defendants' false and misleading statements and omissions in their press releases and other public statements directly caused losses to the Class. On the strength of these false statements, misrepresentations and material omissions in its press releases, announcements and other public statements concerning its financial condition, the Company's stock was artificially

inflated to a Class Period high of $67.80 per share on January 18, 2005, and remained artificially inflated until the end of the Class Period. Thereafter, the stock fell to $38.65 on February 28, 2005, thereby inflicting substantial damages on Lead Plaintiffs and the Class.

377. Until shortly before Lead Plaintiffs filed this Complaint, they were unaware of all of the facts, as described herein, and could not have reasonably discovered the Defendants' fraudulent scheme by the exercise of reasonable diligence.

X. DEFENDANTS ACTED WITH SCIENTER

378. As alleged herein, Defendants acted with scienter in that Defendants knew or recklessly disregarded that the public statements and documents issued and disseminated in the name of the Company were materially false and misleading, knew or recklessly disregarded that such statements and documents would be issued and disseminated to the investing public, and knowingly and substantially participated and acquiesced in the issuance or dissemination of such statements and documents as primary violators of the federal securities laws.

379. Defendants had the opportunity to commit and participate in the wrongful conduct complained of herein. Each was a senior executive officer and/or director of Biogen and thus controlled the information disseminated to the investing public in the Company's press releases, SEC filings and communications with analysts. As a result, each could falsify the information that reached the public about the Company's business and performance. With respect to non-forward looking statements and/or omissions, Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information that they caused to be disseminated to the investing public.

380. Throughout the Class Period, each of the Individual Defendants acted intentionally or recklessly participated in and orchestrated the fraudulent schemes alleged herein to conceal the true risks associated with Tysabri's severe immunosuppressive effect and resulting

life-threatening side effects, to obtain fast-track approval of Tysabri, allowing Biogen to attain its aggressive growth strategy and profit from Tysabri sales and the Individual Defendants to profit from improper insider sales and enormous bonuses.

A. Defendants Directly Participated In, And/Or Had Direct Knowledge Of Or Recklessly Disregarded, The Numerous Warnings And Evidence Of The Severe Immunosuppressive Effects Of Tysabri And Resulting Potential Life-threatening Opportunistic Infections

381. Biogen is the third-largest American biotechnology company and Elan is Ireland's biggest drug company. Working together, these two companies were world-wide leaders in the biotech industry. Moreover, the Individual Defendants were well-educated and experienced in the biotech industry. As alleged herein, throughout the Class Period, Defendants acted intentionally or recklessly disregarded numerous warnings and red flags identifying the severe risks and resulting debilitating effects that Tysabri had on a patient's immune system, leaving patients vulnerable to serious, often life-threatening, opportunistic infections.

382. As alleged herein, the Individual Defendants knew or recklessly disregarded the following facts, alerting them to the dangers of Tysabri: (i) Tysabri, by its very nature because of the way it worked, was an immunosuppressive drug that exposed patients to severe opportunistic infections; (ii) animal studies indicated that Tysabri worked to turn off the immune system; (iii) publications in scientific and medical journals contained similar warnings regarding the severe immunosuppressive effects of Tysabri; (iv) Biogen and Elan had safety committee meetings; (v) scientific meetings were held where top scientists discussed the serious and inherent risks of Tysabri; and (vi) numerous serious opportunistic infections that had already occurred in patients participating in Tysabri clinical trials. Indeed, as discussed above, Defendants were well aware of, or recklessly disregarded, the serious opportunistic infections that occurred during clinical trials because the majority of the MS trials and the Crohn's Disease

trials were completed by January 2004. Thus, the studies would have been unblinded and Defendants would have had full access to, and exhaustively analyzed, their results.

383. Defendants were further aware of, or recklessly disregarded, the serious opportunistic infections that were occurring during the clinical trials through admittedly closely monitoring the Tysabri trials in accordance with the Collaboration Agreement. As discussed above, several confidential sources confirmed Defendants' knowledge and concern of the true risks of Tysabri. In light of the foregoing, Defendants were aware ore recklessly disregarded that Tysabri was unlikely to contribute to Biogen's revenues and earnings to the extent they had led the market to believe

B. <u>Defendants Were Motivated To Commit The Fraud Alleged Herein</u>

1. The Individual Defendants Were Motivated To Commit The Fraud Alleged Herein To Profit From Insider Sales

384. During the Class Period, the Individual Defendants were motivated to engage in the fraudulent practices detailed herein, resulting in the artificial inflation of the Company's stock, so the Individual Defendants and other Biogen insiders could sell their personally held shares at artificially inflated prices.

385. As detailed above, the Individual Defendants, as officers and directors of the Company, were privy to confidential financial information concerning the Company's business, financial condition and future business prospects and outlook. In this capacity, the Individual Defendants had access to material, nonpublic information concerning the Company's true financial condition and the true risks of Tysabri, which, if known to investors, would have necessarily alerted them that the market for Tysabri was much smaller than represented to investors and would contribute minimally to Biogen's revenues and earnings.

386. Notwithstanding the duty not to sell Biogen common stock under these circumstances, or to disclose the non-public, inside information prior to selling their stock, each of the Individual Defendants, and other Company insiders, sold Biogen stock at prices that were artificially inflated by Defendants' materially false and misleading statements and omissions.

387. As is evidenced by the material stock price drop following the February 28, 2005 disclosure, had the market known the truth regarding Biogen's business, the Company's stock price would have been negatively impacted. In total, Biogen insiders sold approximately 2,289,749 shares of Biogen stock for proceeds of approximately $137,233,850. The Individual Defendants themselves sold approximately 1,393,515 shares of Biogen stock for proceeds of approximately $84,212,688, as follows:

WILLIAM H. RASTETTER, EXECUTIVE CHAIRMAN:

CLASS PERIOD SALES:

Date	Number of Shares Sold	Average Share Price	Total Proceeds
5/14/2004	277,651	$58.50	$16,242,584
5/17/2004	130,000	$58.83	$7,635,900
5/19/2004	25,000	$60.03	$1,500,750
5/24/2004	29,081	$62.51	$1,817,714
2/15/2005	120,313	$67.74	$8,149,071
Total	582,045[10]		$35,346,019

[10] Notably, when comparing the Form 4's filed by Defendant Rastetter to the change in his holdings between the periods reported in the 2004 10-K and the 2005 10-K, Plaintiffs were unable to locate Form 4's for approximately 194,651 shares of Biogen stock that Defendant Rastetter apparently sold during the Class Period. Thus, Defendant Rastetter's Class Period sales could be as much as 776,696 shares, rather than the 582,045 shares listed above.

388. Defendant William H. Rastetter's Class Period sales of 582,045 shares for more than $35 million in proceeds represented approximately 25% of his total holdings including vested options. During the Class Period, Defendant Rastetter sold approximately 78% of his shares held at the beginning of the Class Period. Defendant Rastetter's Class Period sales are unusual because he sold ***no*** shares of Biogen since the Biogen/Idec merger in 2003 until his Class Period sales.

JAMES MULLEN, CEO AND PRESIDENT:

CLASS PERIOD SALES:

Date	Number of Shares Sold	Average Share Price	Total Proceeds
5/24/2004	5,500	$ 61.310	$ 337,198
6/01/2004	5,500	$ 62.025	$ 341,051
6/07/2004	5,500	$ 61.780	$ 339,865
6/14/2006	5,500	$ 60.019	$ 330,109
6/21/2004	4,500	$ 57.529	$ 258,881
6/24/2004	1,000	$ 60.094	$ 60,094
6/29/2004	5,500	$ 63.079	$ 346,893
7/09/2004	5,500	$ 62.400	$ 343,990
7/13/2004	5,500	$ 60.594	$ 333,215
7/19/2004	4,500	$ 57.924	$ 260,659
7/26/2004	4,500	$ 53.431	$ 240,442
7/30/2004	1,000	$ 59.859	$ 59,859
8/02/2004	4,500	$ 58.606	$ 263,727
8/10/2004	4,500	$ 55.902	$ 251,561
8/16/2004	4,500	$ 58.420	$ 262,890
8/18/2004	1,000	$ 60.000	$ 60,000
8/23/2004	4,500	$ 59.610	$ 268,242
8/25/2004	1,000	$ 60.003	$ 60,003
8/30/2004	5,500	$ 59.631	$ 327,664

9/07/2004	5,500	$ 61.250	$ 337,150
9/13/2004	5,500	$ 61.793	$ 339,860
9/20/2004	5,500	$ 62.070	$ 341,630
9/27/2004	5,500	$ 59.750	$ 327,750
10/04/2004	5,500	$ 62.620	$ 344,529
10/11/2004	4,500	$ 60.146	$ 330,600
10/18/2004	4,500	$ 57.785	$ 260,034
10/25/2004	1,000	$ 55.947	$ 251,761
10/28/2004	4,500	$ 60.000	$ 60,000
11/01/2004	1,000	$ 58.022	$ 261,096
11/03/2004	5,500	$ 60.002	$ 60,002
11/08/2004	4,500	$ 61.215	$ 336,518
11/15/2004	4,500	$ 58.722	$ 264,250
11/22/2004	4,500	$ 58.722	$ 264,250
11/29/2004	1,000	$ 58.691	$ 264,109
12/02/2004	5,500	$ 60.000	$ 60,000
12/06/2004	5,500	$ 61.076	$ 335,812
12/13/2004	5,500	$ 65.564	$ 360,574
12/20/2004	5,500	$ 65.022	$ 357,606
12/27/2004	5,500	$ 66.043	$ 363,274
01/03/2005	5,500	$ 67.336	$ 370,238
01/10/2005	5,500	$ 66.415	$ 365,374
01/18/2005	5,500	$ 67.769	$ 372,910
01/24/2005	5,500	$ 63.980	$ 351,697
Total	192,000		$ 11,727,370

389. Defendant Mullen's Class Period sales of 192,000 shares for nearly $12 million in proceeds represented 9.1% of his total holdings, including vested options. During the Class Period, Defendant Mullen sold approximately 100% of his shares held at the beginning of the Class Period. Defendant Mullen's sales are unusual when compared to his sales of Biogen stock since the Biogen/Idec merger in 2003 but prior to the Class Period. During that time, he sold

66,700 shares, including vested options, for proceeds of approximately $2,258,852, representing only thirty percent of what he sold during the Class Period.

BURT ADELMAN EXECUTIVE VICE PRESIDENT, DEVELOPMENT:

CLASS PERIOD SALES:

Date	Number of Shares Sold	Average Share Price	Total Proceeds
03/29/2004	12,592	$ 53.700	$ 672,035
05/05/2004	10,000	$ 58.288	$ 582,804
06/28/2004	12,593	$ 63.000	$ 793,359
09/27/2004	12,592	$ 63.000	$ 793,296
12/27/2004	12,593	$ 63.000	$ 793,359
01/03/2005	20,500	$ 67.073	$ 1,374,155
Total	80,870		$ 5,009,008

390. Defendant Adelman's Class Period sales of 80,870 shares for more than approximately $5 million in proceeds represented 16.6% of his holdings including vested options. During the Class Period, Defendant Adelman sold approximately 100% of his shares held at the beginning of the Class Period. Defendant Adelman's sales are unusual when compared to his sales of Biogen stock since the Biogen/Idec merger in 2003 but prior to the Class Period. During that time, he sold 34,500 shares, including vested options, for proceeds of approximately $1,251,728, less than half of the Biogen stock sold during the Class Period.

WILLIAM R. ROHN, CHIEF OPERATING OFFICER:

CLASS PERIOD SALES:

Date	Number of Shares Sold	Average Share Price	Total Proceeds
02/18/2004	25,000	$ 51.814	$ 1,297,583
03/02/2004	125,000	$ 55.679	$ 6,961,587
06/02/2004	50,000	$ 63.489	$ 3,172,396

08/30/2004	50,000	$ 58.596	$ 2,929,252
08/31/2004	25,000	$ 58.633	$ 1,463,542
11/17/2004	75,000	$ 58.087	$ 4,357,848
Total	350,000		$ 20,182,209

391. Defendant Rohn's sales of 350,000 Class Period shares for more than $20 million in proceeds represented 24.1% of his holdings including vested options. During the Class Period, Defendant Rohn sold approximately 91% of his shares held at the beginning of the Class Period. Defendant Rohn's sales are unusual when compared to his sales of Biogen stock since the Biogen/Idec merger in 2003 but prior to the Class Period. During that time he sold approximately 259,550 shares, including vested options, for proceeds of approximately $8,284,541, which is less than half of the total proceeds he received during the Class Period.

<u>THOMAS J. BUCKNUM, GENERAL COUNSEL:</u>

CLASS PERIOD SALES:

Date	Number of Shares Sold	Average Share Price	Total Proceeds
05/04/2004	35,000	$ 58.627	$ 2,051,500
05/25/2004	30,000	$ 62.515	$ 1,875,450
11/30/2004	33,900	$ 59.000	$ 2,100,000
02/18//2005	89,700	$ 67.124	$ 6,021,032
Total	188,600		$ 11,948,082

392. Defendant Bucknum's Class Period sales of 188,600 shares for nearly $12 million in proceeds represented 53.81% of his holdings including vested options. During the Class Period, Defendant Bucknum sold approximately 100% of his shares held at the beginning of the Class Period.

393. Notably, total insider sales during the Class Period, including the Individual Defendants and several other Biogen insiders not named as Defendants, amounted to more than 2.3 million shares totaling approximately $137.2 million in proceeds.

394. As demonstrated in the charts above, the Individual Defendants' stock sales were strategically timed to coincide with key events during the Class Period. For example:

> **February 18, 2004** - the day Defendants announced their intention to seek fast-track approval of Tysabri, Defendant Rohn sold 25,000 shares of Biogen stock for approximately $1.3 million in proceeds, Thomas F. Keller, a Biogen Director, sold 10,350 shares for proceeds of approximately $136,130 and Lynn Schenk, a Biogen Director, sold 112,500 shares for proceeds of approximately $4.7 million, or 59.2%, of her holdings.
>
> **March 2, 2004** - the day Defendants announced Biogen's financial results for the year-ended December 31, 2003, Defendant Rohn sold 125,000 shares for proceeds of approximately $7 million. Only two days later, on March 4, 2004, Defendant Bucknum sold 35, 000 shares for proceeds of approximately $2.1 million.
>
> **May 25, 2004** - the day Defendants announced their submission to the FDA for fast-track approval of Tysabri to treat Defendant Bucknum sold 30,000 shares for proceeds of approximately $1.9 million.
>
> **June 28, 2004** - the day Defendants announced that the FDA had designated the Tysabri Biologics License Application for priority review as a treatment for MS, Defendant Adelman sold 12,593 shares for nearly $800,000 in proceeds.
>
> **November 30, 2004 -** less than a week after the FDA granted approval of Tysabri, Defendant Bucknum sold 33,900 shares reaping proceeds of approximately 2 million.
>
> **February 18, 2005** - the day Defendants told the FDA about the two reported PML cases, Thomas J. Bucknum, Biogen's general counsel, dumped 89,700 shares of stock, reaping approximately $6 million in proceeds for a profit of $1.9 million. Only three days prior, on February 15, 2005, Defendant Rastetter sold 120,313 shares reaping proceeds of $8.15 million and, on February 14, 2005, Craig Schneier sold 3,500 shares for proceeds of $233,100.

395. With respect to the insider sales occurring during the week of February 14 –18, 2005, Stephen L. Meagher, a former federal prosecutor, declared that the timing of these trades, "to put it modestly, looks suspicious." *See LA Times*, "Biogen's General Counsel Resigns Amid

SEC Probe; Thomas Bucknum Sold Shares the Day the Firm Learned That Patients Taking Tysabri Were Ill." (March 4, 2005).

396. Moreover, during the Class Period, each of the Individual Defendants above received proceeds from their stock sales of several times their annual compensation. Specifically, Defendant Rastetter received stock sale proceeds of approximately fifteen times his annual compensation[11] of approximately $2.3 million in 2004, Defendant Mullen received proceeds of approximately five times his annual compensation of approximately $2.3 million in 2004, Defendant Rohn received proceeds of approximately twenty-three times his annual compensation of approximately $872,826 in 2004, and Defendant Adelman received proceeds nearly nine times his annual compensation of approximately $734,000 in 2004.

2. The Individual Defendants Were Motivated To Artificially Inflate The Value Of Biogen's Stock To Receive Substantial Bonuses

397. Defendants were further motivated to conceal the true risks of Tysabri's severe immunosuppressive effects, through the fraudulent schemes discussed herein, to maximize their annual bonuses, which were based largely upon the Company's financial performance and product development.

398. The Proxy Statement on Form 14A filed with the SEC on April 14, 2005 for the period ended December 31, 2004 (the "2004 Proxy") disclosed that the Individual Defendants were awarded bonuses to reward them for "the attainment of short-term ***financial,*** commercial, ***product development*** and individual performance goals." According to the 2004 Proxy,

[11] Per the 2004 Proxy Statement filed with the SEC on April 14, 2005, Defendants' annual compensation includes a base salary, bonus and "other annual compensation."

Defendants' bonuses were based upon "line-of-sight" metrics established by senior management and include key financial objectives as part of the basis of awarding bonuses.

399. By failing to disclose, or recklessly disregarding, the life-threatening effects of Tysabri and avoiding a "black-box" label, which would substantially limit the potential market for Tysabri, discussed above, Defendants were able to achieve "product development" and financial growth goals targets and, accordingly, profit personally from enormous bonuses.

400. As a result of Defendants' improper conduct alleged herein, Defendants were able to achieve their bonus targets. Specifically, as disclosed in the 2004 Proxy, Defendants Rastetter and Mullen received a cash bonus of 141% of their annual compensation, in the amount of $1,345,200. Moreover, Defendant Rohn received a cash bonus equal to 72% of his annual compensation, in the amount of $367,200, Defendant Adelman received a cash bonus of 66% of his annual compensation, in the amount of $288, 960, and Defendant Kellogg received a cash bonus of 64% of his annual compensation, in the amount of $327,750.

401. Coincidentally, the Board of Directors approved these substantial bonuses on February 17, 2005, purportedly the day before Defendants learned of two possible PML cases in MS patients taking Tysabri.

3. Defendants Were Motivated To Market Tysabri As A Combination Therapy With Avonex® To Avoid Cannibalizing Sales Of Avonex®

402. As disclosed in the Company's public filings and press releases, Avonex® is a beta-interferon therapy marketed worldwide by Biogen to treat patients with relapsing forms of MS. According to Defendants, Avonex is the most prescribed therapeutic product for MS worldwide and holds thirty-five percent of the MS market. Thus, Defendants knew that with respect to treating MS, Tysabri and Avonex® targeted the same market and if Tysabri was approved, Biogen would likely lose a substantial portion of Avonex® sales to Tysabri.

403. Accordingly, Defendants initiated an add-on Phase III MS trial (the SENTINEL trial) to test Avonex® in combination with Tysabri, despite known risks of Tysabri. Moreover, as Defendants knew, in patients being treated with Tysabri and Avonex® in combination therapy, Avonex® caused Tysabri serum levels to rise. As a result, patients on the combination therapy had higher serum levels of Tysabri, thereby increasing the already elevated high risks of Tysabri in these co-treated patients. This risk became apparent in the two MS patients who developed PML while on Tysabri and Avonex®.

404. Yet, Defendants failed to disclose known risks of Tysabri, particularly as used in combination with interferons such as Avonex®, so they could market the two drugs together and avoid loss of Avonex® sales. Ultimately, once the FDA learned the truth about Tysabri's risk of life-threatening opportunistic infection, it granted approval of Tysabri only as a monotherapy.

4. Defendants Were Motivated To Conceal Adverse Facts About The Safety Of Tysabri To Enable Them To Profit From Targeting A Much Larger MS Market

405. Defendants were further motivated to conceal the true risks of Tysabri so they could profit substantially from marketing Tysabri to the broadest population possible, as a first-line therapy to treat MS patients without any restrictions. Defendants knew that if the public and the FDA learned of how immunosuppressive and, thus, how dangerous Tysabri truly is, the FDA would likely require a much more prominent, black box safety warning as with other similar immunosuppressive drugs.

406. Defendants knew that a prominent, black box-type warning would substantially shrink the potential market for Tysabri. Accordingly, Tysabri would not be the "blockbuster" drug that would "revolutionize" the treatment of MS that Defendants claimed. Moreover, Biogen's future revenues and earnings from Tysabri would be much smaller than that represented to investors.

407. By concealing the true risks of Tysabri, Defendants were able to gain fast-track approval and begin selling Tysabri approximately eighteen months ahead of schedule, with no restrictive drug label. Accordingly, Defendants were able to receive revenues from Tysabri much sooner.

XI. FRAUD ON THE MARKET ALLEGATIONS

408. At all relevant times, the market for Biogen common stock was an efficient market for the following reasons, among others:

(a) Biogen's common stock was listed and actively traded on the Nasdaq, a highly efficient national market, with more than 344,027,240 shares issued and outstanding.

(b) As a registered and regulated issuer of securities, Biogen filed periodic reports with the SEC, in addition to the frequent voluntary dissemination of information described in this Complaint.

(c) Biogen regularly communicated with public investors through established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures such as communications with the financial press and other similar reporting services;

(d) Biogen was followed by at least thirty different securities analysts employed by major brokerage firms, including A.G. Edwards, Lehman Brothers, Merrill Lynch, Morgan Stanley, Piper Jaffray, SG Cowen Securities, Deutsche Bank, Credit Suisse First Boston and Bear Stearns, who followed Biogen's business and wrote reports

which were distributed to the sales force and customers of their respective brokerage firms. Those reports were publicly available and affected the public marketplace.

409. As a result of the above, the market for Biogen common stock promptly digested current information with respect to the Company from all publicly available sources and reflected such information in the security's price. Under these circumstances, all purchasers of Biogen common stock during the Class Period suffered similar injuries through their purchase of shares at prices which were artificially inflated by the Defendants' misrepresentations and omissions. Thus, a presumption of reliance applies.

XII. NO STATUTORY SAFE HARBOR

410. The statutory safe harbor for certain forward-looking statements does not apply to the misrepresentations and omissions alleged in this Complaint. Many of the statements were not specifically identified as "forward-looking statements" when made. To the extent that there were any properly identified forward-looking statements, there were no meaningful cautionary statements identifying the important then-present factors that could and did cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statement pleaded herein, Defendants are liable nonetheless because at the time each of the misrepresentations was made, the particular speaker(s) knew that the statement was materially false or misleading at that time, and/or the forward-looking statement was authorized and/or approved by an executive officer of Biogen who knew that the statement was materially false and misleading when made.

411. Any warnings or other cautionary language contained in the press releases and other public statements described herein were generic, "boilerplate" statements of risk that would affect any similar company, and misleadingly contained no factual disclosure of any of the

problems affecting the Company which placed the ability of the Company to accurately depict its own financial situation into serious question. As such, any forward-looking statements complained of herein were not accompanied by meaningful cautionary language.

412. Any relevant purported risk disclosures were, in fact, false and misleading in and of themselves, by virtue of the fact that the events which the risk disclosures purported to warn against as contingencies had frequently already become a reality or a certainty.

COUNT I

Violations of § 10(b) Of The Exchange Act And Rule 10b-5 Promulgated Thereunder Against All Defendants

413. Lead Plaintiffs incorporate by reference and reallege all preceding paragraphs as if fully set forth herein.

414. During the Class Period, Defendants used the means and instrumentalities of interstate commerce, the mails, and the facilities of national securities exchanges to: (i) deceive the investing public, including Lead Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Biogen common stock; and (iii) cause Lead Plaintiffs and other members of the Class to purchase Biogen common stock at artificially inflated prices that did not reflect their true value. As the truth became known at the end of the Class Period, the trading price of Biogen common stock fell precipitously. In furtherance of their unlawful scheme, plan, and course of conduct, Defendants took the actions set forth herein.

415. Defendants, individually and in concert, directly and indirectly, by the use of means and instrumentalities of interstate commerce, the mails, and the facilities of national securities exchanges: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and omitted to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading;

and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's common stock, in violation of § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued as primary participants in the wrongful and illegal conduct charged herein. The Individual Defendants also are sued as controlling persons of Biogen, as alleged below.

416. The Individual Defendants' primary liability, and controlling person liability, arises from the following facts, among others: (i) the Individual Defendants were high-level executives and directors at the Company during the Class Period; (ii) the Individual Defendants were privy to and participated in the creation, development, and reporting of the Company's internal budgets, plans, projections and reports; and (iii) the Individual Defendants were aware of the Company's dissemination of information to the investing public they either knew, or recklessly disregarded, was materially false and misleading.

417. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were readily available to them. Defendants' material misrepresentations and omissions were done knowingly, or recklessly, and for the purpose and effect of concealing the truth with respect to Biogen's operations, business, performance, and prospects from the investing public and supporting the artificially inflated price of its common stock.

418. The dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, artificially inflated the market price of Biogen's common stock during the Class Period. In ignorance of the fact that the market prices of Biogen's common stock were artificially inflated, and relying directly or indirectly on the

materially false and misleading statements made by Defendants, or on the integrity of the market in which the common stock trades, or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Lead Plaintiffs and other members of the Class purchased Biogen's common stock during the Class Period at artificially high prices. As the truth eventually emerged, the price of Biogen's common stock fell.

419. At the time of said misrepresentations and omissions, Lead Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Lead Plaintiffs and other members of the Class and the marketplace known the truth with respect to the business, operations, performance, and prospects of Biogen, which was concealed by Defendants, Lead Plaintiffs and other members of the Class would not have purchased Biogen's common stock or would not have purchased such stock at the prices they paid.

420. By virtue of the foregoing, Defendants have violated § 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

421. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and other members of the Class suffered damages in connection with their transactions in the Company's common stock during the Class Period.

COUNT II

Violations of § 20(a) Of The Securities Exchange Act Of 1934
Against The Individual Defendants

422. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

423. Each of the Individual Defendants acted as a controlling person of Biogen within the meaning of § 20(a) of the Exchange Act, as alleged herein. By virtue of their high-level

positions, participation in and/or awareness of the Company's operations and/or intimate knowledge of the statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements Lead Plaintiffs contend were materially false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Lead Plaintiffs to have been misleading prior to and/or shortly after those statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

424. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

425. As set forth above, Biogen and the Individual Defendants each violated § 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are also liable pursuant to § 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

COUNT III

Violations Of § 20A Of The Securities Exchange Act Of 1934 Against The Section 20A Defendants

426. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

427. This claim is asserted against the Section 20A Defendants pursuant to Section 20A of the Exchange Act by Lead Plaintiffs and on behalf of the Class members who purchased Biogen common stock contemporaneously with the sales of the Company's common stock by the Section 20A Defendants.

428. The Section 20A Defendants were privy to confidential, material, non-public adverse information concerning the Company as alleged herein. Notwithstanding the Section 20A Defendants' duty to refrain from trading in Biogen common stock unless they disclosed the foregoing material facts, the Section 20A Defendants sold, in the aggregate, approximately 1,393,515 shares of Biogen common stock during the Class Period and realized proceeds of approximately $ 84.2 million, while in possession of material, non-public adverse information, as set forth above. Moreover, all Biogen insiders sold approximately 2,289,749 shares of Biogen common stock for proceeds of approximately $137.2 million during the Class Period, while in the possession of material, non-public information.

429. The Section 20A Defendants sold their shares of Biogen common stock as alleged above, at market prices artificially inflated by the nondisclosure, and/or misrepresentations, of such material facts in the public statements they made or that they caused the Company to make.

430. The Section 20A Defendants knew or recklessly disregarded that they were in possession of such material information which had not been disclosed to the investing public, including Plaintiffs and Class members who purchased Biogen common stock

contemporaneously with the sales by the Section 20A Defendants on at least the following dates: March 3, 2004, March 31, 2004, April 2, 2004, May 14, 2004, May 21, 2004, June 2 - 3, 2004, June 10, 2004, June 16, 2004, June 21, 2004, June 29, 2004, July 7, 2004, July 8, 2004, July 12, 2004, July 16, 2004, July 26, 2004, August 27, 2004, September 3, 2004, September 8, 2004, September 22, 2004, September 24, 2004, October 5, 2004, October 6, 2004, October 21, 2004, October 22, 2004, October 25, 004, October 26, 2004, October 27, 2004, October 28, 2004, November 3, 2004, November 5, 2004, November 8, 2004, November 11, 2004, November 16, 2004, November 24, 2004, December 2, 2004, December 3, 2004, December 8, 2004, December 13, 2004, December 20, 2004, December 27-29, 2004, January 7, 2005, January 10, 2005, January 27-28, 2005, February 14, 2005, February 15, 2005 and February 18, 2005.

431. Before selling their Biogen common stock, the Section 20A Defendants were obligated to publicly disclose the material information they possessed.

432. By reason of the foregoing, the Section 20A Defendants, by use of the means or instrumentalities of interstate commerce, the mails, and the facilities of the national securities exchanges, employed devices, schemes, and artifices to defraud, and engaged in acts and transactions and a course of conduct which operated as a fraud or deceit upon Plaintiffs and the other Class members who purchased Biogen common stock contemporaneously with the sales by the Section 20A Defendants.

433. Plaintiffs and all other Class members who purchased shares of Biogen common stock contemporaneously with the sales of Biogen stock by the Section 20A Defendants: (i) have suffered substantial damages in that they paid artificially inflated prices for Biogen common stock as a result of the violations of Section 10(b) and Section 20(a) of the Exchange Act and SEC Rule 10b-5 as alleged herein; and (ii) would not have purchased Biogen common

stock at the artificially inflated prices that they paid, or at all, if they had been aware that the market prices had been artificially inflated by Defendants' false and misleading statements.

434. As a result of Plaintiffs' and Class members' purchases of Biogen common stock contemporaneously with the Section 20A Defendants' sales of Biogen common stock, Plaintiffs and Class members have suffered recoverable damages. The Section 20A Defendants are liable to Plaintiffs and the Class as a result of such transactions.

435. The Section 20A Defendants are required to account for all such stock sales and to disgorge their profits or ill-gotten gains.

WHEREFORE, Lead Plaintiffs pray for relief and judgment on behalf of themselves and the Class:

A. Determining that this action is a proper class action and certifying Lead Plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Lead Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be determined at trial, including pre-judgment and post-judgment interest, as allowed by law;

C. Awarding Lead Plaintiffs and the Class their costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Lead Plaintiffs hereby demand a trial by jury.

Dated: October 13, 2006

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CERTIFICATE OF SERVICE

I, Nancy Freeman Gans, hereby certify that a true copy of the above document was served upon the attorney of record for each party via ECF.

/s/ Nancy Freeman Gans
Nancy Freeman Gans